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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-37471

PIERIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**EIN 30-0784346**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
255 State Street, 9 th Floor Boston, MA United States	
(Address of principal executive offices)	**02109 (Zip Code)**

Registrant's telephone number, including area code
857-246-8794

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Name of each exchange on which registered**
None	**N/A**

Securities registered pursuant to Section 12(g) of the Exchange Act:

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ [Do not check if a smaller reporting company]	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, based on the adjusted closing price on that date of $2.75, was $62,342,231.

As of March 20, 2016, the registrant had 39,833,023 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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Forward Looking Statements

This Annual Report on Form 10-K contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties, principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "projects," "predicts," "should," "would," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in this Annual Report on Form 10-K, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ materially. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Annual Report on Form 10-K. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K could negatively affect our business, operating results, financial condition and stock price. All forward-looking statements included in this document are based on information available to us on the date hereof, and except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Annual Report on Form 10-K to conform our statements to actual results or changed expectations.

We have registered trademarks for Pieris®, Anticalin® and Pocket Binding®. All other trademarks, trade names and service marks included in this Annual Report on Form 10-K are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "our Company", "the Company", "Pieris", "we", "us", and "our" refer to Pieris Pharmaceuticals, Inc., a Nevada corporation, and its consolidated subsidiary, Pieris Pharmaceuticals GmbH (formerly known as Pieris AG), a company organized under the laws of Germany. Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015 Pieris AG was transformed to Pieris Pharmaceuticals GmbH as a result of a change in the legal entity,

Currency Presentation and Currency Translation

Unless otherwise indicated, all references to "dollars," "$," "U.S. $" or "U.S. dollars" are to the lawful currency of the United States. All references in this Report to "euro" or "€" are to the currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the Treaty establishing the European Community, as amended. We prepare our financial statements in U.S. dollars.

The functional currency for our operations is primarily the euro. With respect to our financial statements, the translation from the euro to U.S. dollars is performed for balance sheet accounts using exchange rates in effect at the balance sheet date and for revenue and expense accounts using a weighted average exchange rate during the period. The resulting translation adjustments are recorded as a component of accumulated other comprehensive loss.

Where in this Report we refer to amounts in euros, we have for your convenience also in certain cases provided a conversion of those amounts to U.S. dollars in parentheses. Where the numbers refer to a specific balance sheet account date or financial statement account period, we have used the exchange rate that was used to perform the conversions in connection with the applicable financial statement. In all other instances, unless otherwise indicated, the conversions have been made using the noon buying rate of €1.00 to U.S. $1.0906 in the City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2015.

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PART I

Item 1. BUSINESS

Corporate History

General

Pieris Pharmaceuticals, Inc. was incorporated under the laws of the State of Nevada on May 24, 2013 with the name "Marika Inc." On December 17, 2014, Pieris Pharmaceuticals, Inc., Pieris Pharmaceuticals GmbH ("Pieris GmbH") and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. Prior to the Acquisition, as defined below, Pieris pursued a business of an errand concierge service online marketplace.

On December 5, 2014, Pieris completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock split became 13,863,647 shares of common stock outstanding immediately thereafter. On December 16, 2014, prior to the closing of the Acquisition, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc.," and increase its authorized capital stock from 75,000,000 shares of common stock, par value $0.001 per share, to 300,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share.

On December 17, 2014, Pieris, Pieris GmbH and the former stockholders of Pieris GmbH entered into an Acquisition Agreement, or the Acquisition Agreement. Pursuant to the Acquisition Agreement, the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH to Pieris in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition. The Acquisition closed on December 17, 2014.

In connection with the Acquisition and pursuant to a Split-Off Agreement, dated December 17, 2014 among Pieris, Marika Enterprises Inc. and Aleksandrs Sviks, or the Split-Off Agreement, and a general release agreement, Pieris transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock, or the Split-Off. Upon the closing of the Acquisition and the Split-Off, Pieris discontinued its pre-Acquisition business plans and is now pursuing only the business of Pieris GmbH.

Upon the closing of the Acquisition, Pieris ceased to be a "shell company" under applicable rules of the SEC. On December 17, 2014, in connection with the Acquisition, our Board of Directors changed our fiscal year from a fiscal year ending on June 30 to one ending on December 31 of each year, which was the fiscal year of Pieris GmbH.

On December 17, 2014, Pieris entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain accredited investors, or the Investors, providing for the issuance and sale to such investors of an aggregate of 6,779,510 shares of our common stock in a private placement offering conducted through a series of closings occurring on December 17, 18 and 23, 2014, at a purchase price per share of $2.00 and for aggregate gross proceeds to us of $13.56 million, or the Private Placement. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.04 million. Northland Securities, Inc. and Katalyst Securities, LLC served as co-exclusive placement agents, or the Placement Agents, for the Private Placement.

At the closings of the Private Placement we issued to the Placement Agents and their designees, warrants, or the Placement Warrants, to acquire up to 542,360 shares of our common stock at an exercise price of $2.00 per share. Each of the Placement Warrants is exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance.

In connection with the Private Placement, we also entered into a registration rights agreement, or the Registration Rights Agreement, with the Investors, the former stockholders of Pieris GmbH and the holders of Placement Warrants. Pursuant to the terms of the Registration Rights Agreement, the Company agreed to file with the SEC, within 90 days following December 17, 2014, a registration statement to register for resale all of the 6,779,510 shares of the Company's common stock issued in the Private Placement, as well as an additional 20,000,000 shares of our common stock which the Company issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition, and an additional 542,360 shares of common stock issuable to holders of the Placement Warrants. The registration statement was effective on May 11, 2015. If the registration statement ceases to be effective during the required effectiveness period, except as permitted under the Registration Rights Agreement, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock on every monthly anniversary of such failure and prorated for any portion of a month, until it is cured or all of such selling stockholder's securities to be registered hereunder have been or may be sold without restriction pursuant to Rule 144. Furthermore, if the Company fails to timely file reports required to be filed by us pursuant to Section 13(a) or 15(d) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Company will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock. Notwithstanding the foregoing, the Company will not be obligated to make any such payments with respect to any of the securities to be registered thereunder that we are unable to register due to limits imposed by the SEC's interpretation of Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act. Under the Registration Rights Agreement, subject to exception in certain circumstances or pursuant to the Acquisition, as applicable, we have agreed to keep such registration statement effective until the later of December 17, 2016 and such time as all of the securities to be registered thereunder have been sold under the registration statement or pursuant to Rule 144 or may be sold without restriction pursuant to Rule 144. If there is not an effective registration statement covering the resale of the securities to be registered by such registration statement at any time prior to December 17, 2015, then the selling stockholders will have "piggyback" registration rights with respect to any such securities that are not eligible for resale pursuant to Rule 144 without volume or manner of sale restrictions in connection with any other registration statement we determine to file that would permit the inclusion of those shares.

On July 6, 2015 we closed a public offering of an aggregate of 9,090,909 shares of our common stock at a purchase price of $2.75 per share. On July 24, 2015 the underwriters exercised their over-allotment option to purchase 1,211,827 additional shares of our common stock at the public offering price of $2.75, the sale of which closed on July 28, 2015. Gross proceeds raised by the Company in the offering, including the exercise of the over-allotment option, were $28.3 million and net of equity issuance costs are $25.8 million. We intend to use the net proceeds from the offering to fund research and development, including preclinical and clinical research and development of our drug candidates, working capital and general corporate purposes.

Pieris Pharmaceuticals, Inc. is a holding company and the sole stockholder of Pieris GmbH. The corporate headquarters and research facility of Pieris GmbH are located in Freising, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development in Australia.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, establishes a class of company called an "emerging growth company," which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than $1 billion during its most recently completed

fiscal year. Additionally, Section 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, establishes a class of company called a "smaller reporting company," which generally is a company with a public float of less than $75 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is $0, had annual revenues of less than $50 million during the most recently completed fiscal year for which audited financial statements are available. We currently qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain extended accounting standards and exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation the following:

- An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.
- An emerging growth company is exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and financial statements, commonly known as an "auditor discussion and analysis."
- An emerging growth company is not required to hold nonbinding advisory stockholder votes on executive compensation or any golden parachute payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of internal controls over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act of 2002.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in its registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earlier of (i) December 31, 2019, the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of $75 million or more as of the last business day of our most recently completed second fiscal quarter, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Business Overview

We are a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Our proprietary Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies.

Anticalin® proteins are a class of low molecular-weight therapeutic proteins derived from lipocalins, which are naturally occurring low-molecular weight human proteins typically found in blood plasma and other bodily fluids. Anticalin®-branded proteins function similarly to monoclonal antibodies, or mAbs, by binding tightly and specifically to a diverse range of targets. An antibody is a large protein used by the immune system that recognizes a unique part of a foreign target molecule, called an antigen. We believe Anticalin proteins possess numerous advantages over antibodies in certain applications. For example, Anticalin proteins are small in size and are monomeric, meaning single protein units rather than a multi-protein complex. Therefore, we believe Anticalins are generally more stable biophysically than tetrameric monoclonal antibodies, composed of four protein subunits, potentially enabling unique routes of drug administration such as pulmonary delivery. Higher-molecular-weight entities such as antibodies are often too large to be delivered effectively through these methods. In addition, Anticalin proteins are monovalent in structure, which means they bind to a single cell surface receptor and which may avoid the risk of cross-linking of cell surface receptors where such receptors are a therapeutic target. Antibody-mediated cross-linking can occur when each of the two “arms” of an antibody binds to a cell surface receptor and brings these receptors into close proximity, which can lead to aggressive cell growth that is characteristic of cancer. While our basic Anticalin proteins have only a single binding site and are not subject to such cross-linking, our Anticalin-branded technology is also modular, which allows us to design Anticalin proteins to bind with specificity to multiple targets at the same time. This multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Moreover, unlike antibodies, the pharmacokinetic, or PK, profile of Anticalin proteins can be adjusted to potentially enable program-specific optimal drug exposure. Such differentiating characteristics suggest that Anticalin proteins have the potential, in certain cases, to become first-in-class drugs.

We have access to intellectual property rights directed to various aspects of our Anticalin® technology platform, allowing for development and advancement of our platform and drug candidates. We believe our ownership and/or license of our Anticalin platform provides us with a strong intellectual property position, particularly where we are seeking to address targets and diseases in a novel way and for which there is existing monoclonal antibody intellectual property.

Our core Anticalin® technology and platform were developed in Germany, and we have collaboration arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi Sankyo Company Limited, or Daiichi Sankyo, and Sanofi Group, or Sanofi, pursuant to which our Anticalin platform has consistently achieved its development milestones. Furthermore, we established a collaboration with F.Hoffmann—La Roche Ltd. and Hoffmann—La Roche Inc., or Roche in December 2015. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms in Australia, which increasingly are being handled through Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris.

We believe that the drug-like properties of the Anticalin® drug class were demonstrated in Phase Ia/Ib clinical trials with our two Anticalin-branded drug candidates PRS-080 and PRS-050. Our anti-VEGF-A drug candidate, PRS-050, designed to inhibit blood vessel growth in solid tumors, was investigated in solid tumor patients. VEGF-A is a protein that induces growth of blood vessels, and anti-VEGF-A drug aim to inhibit the blood supply to solid tumors. In a phase Ib multi-ascending dose trial performed under governance by the German Federal

Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM*), PRS-050 was shown to be generally safe and well-tolerated, and we were not able to detect any anti-drug antibodies, or ADAs, following administration of a total of 144 doses with five or more doses to 17 patients. We believe that these results demonstrated that there was no apparent immune response against PRS-050. Furthermore, dose-proportional PKs, pharmacology and biomarker activity were observed in the trial, which we believe demonstrates that PRS-050 engaged with its intended target VEGF-A in those patients. Despite these results, we, decided not to advance PRS-050 based on our belief that PRS-050's mode of action (the way in which it functions in the body, namely, antagonizing VEGF-A) was not sufficiently differentiated over the modes of action of already-marketed therapies, such as bevacizumab and aflibercept, to create enough economic value in the drug market to support continued development of PRS-050 as a competitive product candidate. While we have not advanced development of PRS-050 since that time for the aforementioned strategic and business reasons, we believe that the positive results from this clinical trial generally support continued investment in our Anticalin drug candidates.

Our current development plans focus mainly on three drug candidates, PRS-080, PRS-060 and our PRS-300 series.

PRS-080 is an Anticalin® protein that binds to hepcidin, a natural regulator of iron in the blood. An excess amount of hepcidin can cause functional iron deficiency, or FID, which often cannot be treated adequately with iron supplements and can lead to anemia. PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with chronic kidney disease, or CKD, particularly in end-stage renal disease patients requiring dialysis. We believe that by blocking the actions of hepcidin, PRS-080 will serve to address anemia by mobilizing iron for incorporation into red blood cells. Furthermore, we engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter timeframe than antibodies, which typically have a half-life of two weeks or greater. We believe a shorter residence time in the body may be a superior approach for countering excess hepcidin, as physiological levels of hepcidin in these patients are relatively high (nanomolar concentration), and in theory such high concentrations will quickly saturate an administered binding drug. As a result, frequent administration of a drug may be required in order to sufficiently antagonize, or suppress the effect of, the target. The longer residence time of a mAb, could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. PRS-080 was investigated in a single-ascending dose Phase Ia trial in healthy subjects under governance by the BfArM. This study demonstrated excellent safety and tolerability of PRS-080 as well as dose-proportional pharmacological activity and pharmacokinetics. The inhibition of hepcidin and the subsequent change in parameters of iron metabolism such as the increase in serum iron and transferrin saturation confirmed the mode of action of PRS-080. This study was completed in 2015. The next phase of clinical development is a Phase Ib study in CKD patients requiring hemodialysis, which commenced in the first quarter of 2016 and is expected to be completed in 2016 in order to study safety and pharmacological activity in CKD patients.

The second Anticalin® drug candidate, PRS-060, binds to the IL-4 receptor alpha-chain (IL-4RA), thereby inhibiting the actions of IL-4 and IL-13, two cytokines (small proteins mediating signaling between cells within the human body) known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases. The small size and biophysical stability of PRS-060 enables direct delivery to the lungs, such as through the use of an inhaler, which we believe will enable high pulmonary concentrations of the drug candidate to be achieved at substantially lower doses than would be reached with antibodies that are systemically delivered. Further, PRS-060 has a short systemic residence time which we believe may avoid undesired target engagement outside of the desired area in the lungs. PRS-060 is currently undergoing IND-enabling activities, and we intend to begin a Phase I clinical trial with PRS-060 in 2017.

The third Anticalin®-based drug candidate, PRS-343, is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. PRS-343 is the result of a genetic fusion of a variant of the HER2-targeting antibody trastuzumab with an Anticalin specific for CD137. The mode of action of this CD137/ HER2 bispecific

is to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials.

PRS-343 is a member of our second set of oncology drug candidates known as the 300-Series "platform within a product" opportunity in immuno-oncology. The 300-Series Anticalin® proteins target checkpoint or, like PRS-343, immune-stimulatory proteins and define a variety of multifunctional biotherapeutics that genetically link two distinct Anticalin proteins together or an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein. Checkpoint proteins are proteins that help the development of an immune response or downregulate the response, for example when an infection is eliminated while co-stimulatory proteins (e.g. CD-137) upregulate the immune response.

Strategy

Our goal is to become a fully integrated biotechnology company by discovering and developing Anticalin® based therapeutics to target validated disease pathways in a unique and transformative way, and later developing and commercializing our products. We intend to take advantage of our operational experience in technology development and our history of successful partnerships and collaborations to pursue additional partnerships that will help provide us the experience we need to bring Anticalinbased drug candidates to market in a number of indications. We intend to engage with partners for many of our programs in a combination of geographic and indication-based arrangements to maximize our business opportunities. We also intend to retain certain development and commercial rights on selected products as our experience in drug development grows. Key elements of our strategy include:

- ***Continue to build our platform by entering into new partnerships and license and collaborative arrangements and advancing our currently-partnered programs.*** We have entered into partnership and collaborative arrangements with pharmaceutical companies in a diverse range of therapeutic areas and geographies. We have active partnerships with global pharmaceutical companies, such as Sanofi, Daiichi Sankyo and Roche. Together with our partners, we intend to advance multiple drug candidates through preclinical studies and to select further drug candidates for clinical development in the future. We will also continue to seek to engage with new pharmaceutical partners that can contribute funding, experience and marketing ability for the successful development and commercialization of our current and future drug candidates.
- ***Advance PRS-080 in clinical trials in anemia patients.*** PRS-080 was investigated in a single-ascending dose Phase Ia trial in healthy subjects in 2015 under governance by the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM*). This study demonstrated excellent safety and tolerability of PRS-080 as well as dose-proportional pharmacological activity and pharmacokinetics. The inhibition of hepcidin and the subsequent change in parameters of iron metabolism such as the increase in serum iron and transferrin saturation confirmed the mode of action of PRS-080. The next phase of clinical development, has commenced in the first quarter of 2016, is a Phase Ib study in CKD patients suffering from FID-anemia, which is expected to be completed in 2016 to study safety and pharmacological activity in CKD patients.
- ***Advance PRS-060 through IND-enabling studies and subsequently into first-in-man trial.*** We have a strong preclinical pipeline of Anticalin drug candidates in diverse indications such as severe asthma (PRS-060) and immuno-oncology (PRS-343). We will continue to move forward with preclinical and discovery work on these drug candidates with the goal of advancement into clinical trials on a data-driven basis.

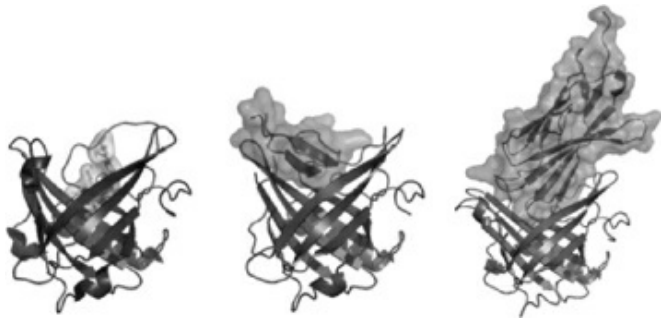
- ***Advance PRS-343 through IND-enabling studies and subsequently into first-in-patient trial.*** IND-enabling studies are underway with Good Manufacturing Practice ("GMP") and preclinical toxicology scheduled for 2016.
- ***Pursue and broaden opportunities for our Anticalin technology.*** We intend to continue to identify, vet and pursue opportunities to develop novel Anticalin therapeutics for oncology, pulmonary disease and a variety of additional diseases, as we continue to improve on the Anticalin platform technology.

Anticalin platform technology

Our platform technology focuses on low molecular-weight Anticalin® proteins that bind tightly and specifically to a diverse range of targets. Anticalin proteins are derived from human proteins called lipocalins, which are naturally occurring low-molecular weight human proteins of approximately 18 to 20kDA molecular mass typically found in blood plasma and other bodily fluids. The lipocalin class of proteins defines a group of extracellular specific-binding proteins that, collectively, exhibit extremely high structural homology, yet have an uncharacteristically low amino acid sequence identity (less than 20%), making them attractive "templates" for amino acid diversification. Lipocalins naturally bind to, store and transport a wide spectrum of molecules. The defining attributes of the 12-member human lipocalin class and, by extension, Anticalin proteins, engineered from the lipocalin class of proteins, are a four-loop variable region and a rigidly conserved beta-barrel backbone, which, together, form a cup-like binding pocket. The below graphic shows both tear (left) and NGAL (right) lipocalins together with their natural ligands.

Anticalin® proteins are created from either tear lipocalin, found in human tear fluid, or NGAL lipocalin, a protein involved in the innate immune system, by making discreet mutations in the genetic code for the binding regions. These mutations have the potential to lead to highly specific, high-affinity binding for both small and large molecular targets. Random mutations are introduced at pre-defined positions involved in endogenous ligand engagement, creating exponentially diverse pools of Anticalin proteins, the most potent and well behaved of which are selected and optimized in a customized manner through *in vitro* selection. Using techniques such as phage display, a successful technique in antibody-based drug discovery, to build and refine antibody libraries, the ability to introduce diversity and then select for the best binders among a large pool of Anticalin proteins gives us the opportunity to select Anticalin proteins for a wide variety of targets. The flexibility inherent in the Anticalin proteins' cup-like structure allows us to choose both small-molecule targets that fit inside the 'cup' as well as larger protein targets that can be bound by the Anticalin proteins' outward-facing arms. Our Phase Ia/Ib trial for PRS-080 and PRS-050 indicated that Anticalin proteins may be non-immunogenic and thereby have the potential to exhibit a favorable safety profile.

The below graphic demonstrates Anticalin® drug candidates binding to a small molecule (left), a small protein target (hepcidin, center) and a large protein target (CTLA4, right):



To obtain a specific Anticalin® protein, we take advantage of the breadth of our proprietary Anticalin libraries, generated through our protein engineering expertise. We have created, and will continue to create, proprietary Anticalin libraries by rationally diversifying the lipocalin regions that are responsible for ligand binding, applying different libraries to different types of targets. By utilizing bacterial production from the earliest stages of drug discovery through Current Good Manufacturing Practice, or cGMP, manufacturing, we have created a seamless platform that improves the quality, yield and cost-effectiveness of our drug candidates. However, Anticalin protein manufacturing is not limited to bacterial systems, with the underlying expression system being driven on a program-by-program basis. See "—Manufacturing" below.

As targeted, protein-based molecules, Anticalin® proteins also function similarly to monoclonal antibodies, thereby offering many of the same favorable qualities, including:

- *High specificity to their targets*. Like monoclonal antibodies, Anticalin proteins can bind their targets without binding other molecules, even molecules with very similar chemical structures or amino acid sequences, allowing for more effective treatments through, for example, minimizing off-target effects.
- *Tight binding and effective biological activity at their targets*. Like monoclonal antibodies, Anticalin proteins are able to bind their targets at subnanomolar affinities. Anticalin proteins can potentially achieve desirable biological effects by inhibiting an undesired or inducing a desired cell activity by binding to cell-surface receptors or their ligands.
- *Human origin.* Like many monoclonal antibodies in development and marketed today, Anticalin proteins are derived from a natural class of circulating human proteins. Their human origin increases the likelihood that Anticalin proteins will not be recognized as foreign by the immune system and subsequently rejected.
- *Scalability for large scale production*. Like monoclonal antibodies, Anticalin proteins lend themselves to large-scale production, yet can also be produced in a range of expression systems ranging from prokaryotic (bacterial) to eukaryotic (animal, plant, fungal) cells. Anticalin proteins can take advantage of several well-understood and widely practiced methods of protein production both in small amounts for preclinical testing and at larger scale for clinical trials and commercial production.

While often compared to monoclonal antibodies, Anticalin® proteins, we believe, offer several advantages over antibodies, including:

- *Small size and biophysical stability*. Anticalin proteins are small in size and are monomeric. Therefore, we believe Anticalins are generally more stable biophysically than tetrameric monoclonal antibodies, potentially enabling unique routes of administration to target diseases, such as pulmonary delivery. Higher-molecular-weight entities such as antibodies are often too large to be delivered effectively through these methods. We believe Anticalin proteins will also be less expensive to manufacture than

antibodies due to their lower molecular weight and less bulky structure as well as the ability to use the prokaryotic-based manufacturing systems, a less costly manufacturing system than mammalian cell-based manufacturing systems.

- *Optimization of half-life*. Anticalin proteins can be engineered to have a half-life that is optimal for the indication area and a desired dosing schedule. Antibodies typically have half-lives of two weeks or longer, whereas Anticalin proteins can be engineered to have half-lives from hours to weeks, depending on the half-life extension technology employed, if any. This optionality allows us to exert greater control over the amount of circulating Anticalin protein in the blood and the amount of time such Anticalin proteins circulate in the blood, depending on the underlying biology we are trying to address.
- *Modular platform for higher-order multispecificity and avoidance of cross-linking.* Our Anticalin technology is modular, allowing for monovalent or multivalent target engagement, including multispecificity within a single protein. We believe that a monovalent "backbone" is an advantage in situations where pure antagonism of certain cellular receptors is desired. The dual-binding nature of monoclonal antibodies, which have two "arms," can be a disadvantage in cases when the antibodies bind to and cross-link cell-surface receptors. Such cross-linking often leads to undesirable activation of the cells bearing those receptors. Single-action (monovalent) Anticalin proteins have only a single binding site and are thus not subject to cross-linking. Further, when it is called for by the biology we are addressing, we can create multispecific Anticalin proteins that can simultaneously bind (i) two or more different targets or (ii) different epitopes, the specific piece of an antigen to which an antibody binds, on the same target by genetically linking Anticalin proteins with distinct specificities on a common cDNA strand. We believe this multispecificity offers advantages in biological settings where binding to multiple targets can enhance the ability of a drug to achieve its desired effects, such as killing cancer cells. Unique Anticalin proteins can be pieced together and undergo simultaneous target engagement as a single fusion protein, without generally compromising on manufacturability.

We believe that drug-like properties of the Anticalin® drug class were demonstrated for PRS-050, our anti-VEGF-A Anticalin-branded drug candidate designed to inhibit blood vessel growth in solid tumors, in a Phase Ib clinical trial in solid tumor patients. Although we are not advancing the development of PRS-050 in oncology for strategic and business reasons, we were able to demonstrate in 26 patients with advanced solid tumors that this drug candidate engaged its target with nanomolar affinity, did not generate any detectable ADAs, and has an activity that can be confirmed by biomarker activity, target engagement assays and known on-target effects such as hypertension. In this trial, 17 patients received five or more doses of PRS-050. We believe that the positive results from the Phase Ib clinical trial for PRS-050 lends support to the future success of our drug candidates currently in development.

PRS-080 showed excellent safety and tolerability with no infusion reactions, no signs of hypersensitive and no Severe Adverse Events in a Phase Ia trial in healthy subjects. Besides dose-proportional pharmacokinetics, pharmacologic activity confirming the mode of action of PRS-080 was demonstrated. A dose-dependent increase of the area under the serum iron concentrations was observed to a statistically significant amount compared to healthy subjects receiving placebo (P=0.0023) subsequent to reduction of hepcidin blood levels, further demonstrating the drug-like properties of the Anticalin® drug class and supporting further development of PRS-080 in FID-anemic patients.

Implementation of our Anticalin Platform Technology: Our Drug Candidates *Pipeline*

Each of our drug candidates is in the early stage of development, and we anticipate that it will likely be several years before any of our drug candidates could be commercialized. The following table summarizes the status of our current drug candidates and programs:

Product Candidate and Target	Indication	Stage of Development	Upcoming Milestone(s)	Commercial Rights
PRS-080 targeting Hepcidin	FID, Anemia of chronic kidney disease	Preclinical → IND Enabling Studies → Phase 1	▪ Data from Phase Ib in patients expected by the end of 2016	Pieris
PRS-060 targeting IL-4RA	Asthma	Preclinical → IND Enabling Studies	▪ Expect to complete IND Enabling Studies in 2017 ▪ Planned Phase I clinical study to begin in 2017	Pieris
PRS-343 targeting CD137 and HER2	Immuno Oncology	Preclinical → IND Enabling Studies	▪ Expect to complete IND Enablings Studies in 2017 ▪ Planned Phase I clinical study to begin in 2017	Pieris
PRS-300 series targeting immune checkpoints	Oncology	Preclinical	▪ Expect to complete preclinical phase in 2016	Pieris

PRS-080 targeting hepcidin in CKD-related FID-anemia

PRS-080 is an Anticalin® drug candidate targeting hepcidin, a peptide mediator that is an important negative regulator of iron absorption and storage, derived from the naturally occurring human lipocalin known as NGAL. The normal function of hepcidin is to maintain equilibrium in iron supply for red blood cell production by binding to ferroportin, the protein that transports iron from the inside of a cell to the outside, inducing its internalization and subsequent degradation. The binding of hepcidin to ferroportin reduces the iron uptake from the intestine into the body and inhibits iron mobilization from cellular stores into red blood cells. An excess amount of hepcidin can cause FID, which often cannot be treated adequately with iron supplements and can lead to anemia. According to a 2009 publication by Young and Zaritsky in the Clinical Journal of the American Society of Nephrology, lowering hepcidin levels or antagonizing its actions would reverse the negative effects of inflammation on red blood cell formation by allowing mobilization of stored iron and improved iron absorption.

PRS-080 has been designed to target hepcidin for the treatment of FID in anemic patients with CKD, particularly in end-stage renal disease patients requiring dialysis, to allow them to mobilize iron that is trapped in iron storage cells for use in the creation of red blood cells. We have also engineered PRS-080 to have a half-life of less than a week, so that following administration, it is expected to clear from the human body in a much shorter timeframe than antibodies, which typically have a half-life of two weeks or greater. This half-life was achieved by covalently linking PRS-080 to a specific polyethylene glycol, or PEG, in order to extend the serum half-life of the combined molecule to desirable levels. Since hepcidin is constantly produced by the body, we believe that a frequent, e.g. once per week, dosing interval will be optimally suited to interfere with hepcidin function. A half-life of about three days and a shorter residence time than mAbs is then in turn more compatible with the dosing schedule. A longer mAb-like residence time is not seen as advantageous, but rather could lead to the accumulation of both the drug and the target beyond the typical residence time of hepcidin, resulting in large quantities of hepcidin bound to mAbs. We completed a Phase Ia single-ascending dose clinical trial with PRS-080 in healthy volunteers in 2015. The trial was conducted in accordance with German law at a clinical site in Neu-Ulm, Germany, that belongs to Nuvisan GmbH, our contract research organization, or CRO. Results from

this trial were presented at the 2015 Annual Conference of the American Society of Hematology (http://www.bloodjournal.org/content/126/23/536). Based on the data obtained we are now continuing further development of PRS-080 in a Ib clinical study in CKD 5 patients requiring hemodialysis and which we expect to complete by the end of 2016. The data are intended to provide clinical-trial support for subsequent applications in the U.S.

Chronic kidney disease

According to the American Kidney Fund, approximately 31 million individuals in the United States have CKD (Stages 1-5). The proportion of CKD patients with anemia increases with the severity and stage of CKD, however according to a September 2013 competitive landscape report conducted by Tech Atlas Group, overall rates of individuals with anemia among the CKD population are approximately 30%, and according to a 2004 study by McClellan et al., Current Medical Research and Opinion, approximately 47% of the CKD patients studied were found to be anemic. Extrapolating these percentages based on the CKD population of 31 million individuals, we believe that approximately 9.3 to 14.6 million individuals in the United States with CKD are anemic. CKD (Stage 5), also known as End-Stage Renal Disease, or ESRD, is the final stage of chronic kidney disease with approximately 0.64 million patients in the US as of December 31, 2012 according the U.S. Renal Data System, USRDS 2014 Annual Data Report. The Tech Atlas Group report also estimates that approximately 70%, or approximately 0.45 million, of CKD (Stage 5) patients suffer from anemia. Anemia related to CKD is currently treated by injectable recombinant protein erythropoiesis, or red blood cell production, stimulating agents, or rESAs—including Epogen, Aranesp, and Procrit—with iron supplementation or a red blood cell transfusion. Based on the reported revenues of companies that market and sell rESAs, we believe that global sales of injectable rESAs were $6.3 billion in 2012, the vast majority of which were for renal indications.

Anemia and functional iron deficiency in the CKD population

Anemia is a serious medical condition in which blood is deficient in red blood cells, and hemoglobin, leading to inadequate oxygen delivery to tissues and cells throughout the body. Anemia is generally said to exist when hemoglobin is less than 13 g/dL in men and 12 g/dL in women. Anemia has a number of potential causes, including nutritional deficiencies, iron deficiency, bone marrow disease, medications, and abnormalities in production of or sensitivity to erythropoietin, a hormone that controls red blood cell production. Anemia is a frequent and severe consequence of CKD. In addition, within the CKD population, anemia may be caused by FID. FID exists when, despite adequate stores, iron cannot be mobilized for erythropoiesis. In this case, despite treatment with exogenous erythropoietin and iron supplements, iron is still deficient. FID-anemic patients can be identified and selected for therapy using marketed laboratory tests for iron metabolism. The USRDS 2014 Annual Data Report estimates that as of 2012, approximately 409,000 individuals with ESRD are presently on hemodialysis. According to the results of a 2013 research analysis conducted for us by Artisan Healthcare Consulting, which, among other things, pooled research results from nephrologists in the United States, approximately 82% of the hemodialysis patient population are anemic, and that among the anemic hemodialysis patient population, up to 23% are FID-anemic. Based on the estimated 409,000 individuals with ESRD on hemodialysis, we believe that approximately 335,000 ESRD patients on hemodialysis are anemic and approximately 0.08 million individuals are FID-anemic.

Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases, and death. These morbidity and mortality risks have been clearly shown in the CKD population, where in patients age 66 and older, anemic patients with mid-stage CKD (Stage 3) have a 149% increase in cardiovascular events, and patients with severe CKD (Stage 4 and 5) have a 24% increase in cardiovascular events, in each case versus non-anemic patients in the same group, according to a paper published in 2006 in the peer-reviewed journal *Blood*. Similarly, compared to non-anemic patients, anemia increases the mortality rate by 199% in mid-stage CKD, and 59% in severe CKD. Successful treatment of anemia significantly improves patients' quality of life, especially with respect to vitality, fatigue and physical function. In addition, patients whose anemia has been successfully treated have demonstrated lower mortality rates, less frequent hospitalization, and decreases in cardiovascular morbidity.

Challenges in using conventional therapy

We believe CKD patients with FID-anemia are especially poorly served. These patients have adequate stores of iron but this iron is not efficiently incorporated into red blood cell precursors through rESAs and iron supplements. According to the 2009 publication by Young and Zaritsky in the Clinical Journal of the American Society of Nephrology, this imbalance in iron metabolism is a result of a high level of circulating hepcidin in the blood stream. We believe existing therapies are limited in that they do not have an impact on hepcidin or, in the case of rESAs, patients often become resistant to the therapy.

Our potential solution: binding hepcidin with PRS-080

We have engineered PRS-080 so that it binds to hepcidin and reduces the impact of hepcidin's negative regulation on iron mobilization. We believe that by blocking the actions of hepcidin, PRS-080 will serve to address anemia by mobilizing iron for incorporation into red blood cells.

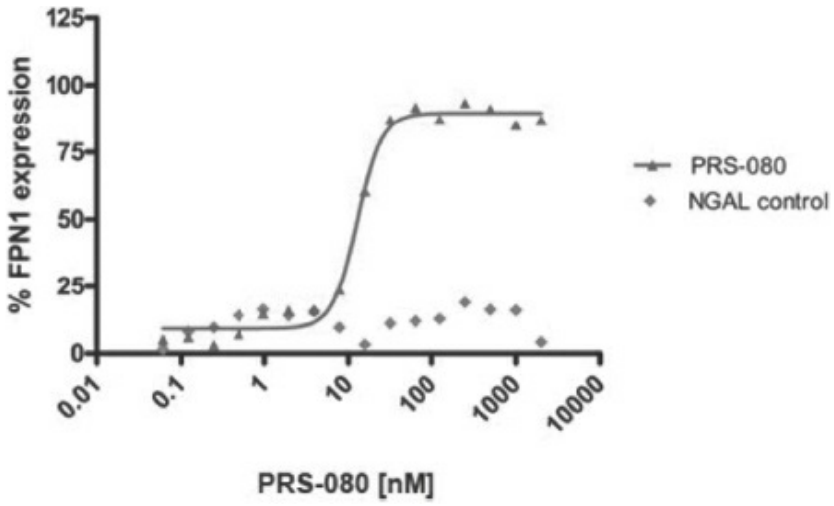
In patients suffering from anemia of CKD, and specifically in patients with FID, hepcidin is frequently produced by the body in abnormally large amounts. Therefore, we believe that the best way to inhibit its function is to administer an inhibitor frequently, such as once a week. Our approach will use PRS-080 in connection with a conjugated PEG30 molecule, a well-known half-life extender, potentially allowing the drug sufficient residence time. Once coupled to PEG30, PRS-080 is intended to have a half-life that will be optimally suited for dosing anemic patients with CKD. In contrast, antibodies typically have a half-life of two to three weeks. Such a long half-life renders antibodies unsuitable for frequent administration and elimination of a circulating target protein like hepcidin because such antibodies tend to accumulate the target after binding due to their own long residence time in the body with the associated risk of bound hepcidin being released by antibodies that are still circulating in the blood.

Preclinical data

Our preclinical studies targeted the cynomolgus monkey orthologue of hepcidin, which has a high degree of similarity (96% identity) with human hepcidin. PRS-080 was found to bind with high affinity to the cynomolgus monkey version of hepcidin. We performed a dose finding study in cynomolgus monkeys, testing intravenous 30-minute infusions as well as subcutaneous injections of PRS-080. We also carried out a 4-week repeated dose toxicology study with intravenous infusions of PRS-080 for 30 minutes every other day. Our work included toxicokinetic and ADA measurements. During the study, safety pharmacology parameters on the cardiovascular system and respiration were monitored and all safety endpoints were met. Our preclinical studies also examined a different NGAL-derived Anticalin®, or surrogate molecule, which targets rat hepcidin in a rat model of inflammation-induced anemia. In these studies, administration of the surrogate molecule once per day or every other day inhibited the manifestation of anemia in the rats over the course of a three-week period.

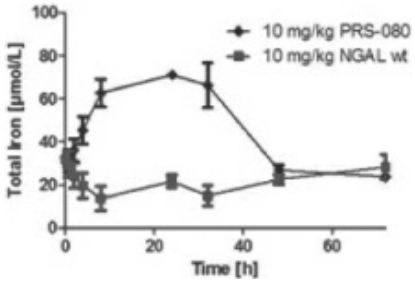
Hepcidin binds to ferroportin and induces its internalization and subsequent degradation, thus disabling iron mobilization from cells. PRS-080 binds strongly to hepcidin and inhibits its activity as shown in potency assays. These in vitro potency studies showed that the hepcidin-induced internalization of ferroportin is inhibited by PRS-080 in a dose-dependent manner. PRS-080 allowed for the restoration of ferroportin expression, overcoming the hepcidin-induced down-regulation, whereas NGAL alone did not have a similar effect on ferroportin expression.

The below chart demonstrates the percentage of expression of ferroportin, % FPN1, by PRS-080 mediated inhibition of hepcidin in an in vitro potency assay with ferroportin transfected 293 cells, wherein at 20 nM, hepcidin induces internalization of ferroportin which is reversed by PRS-080 in a dose dependent manner:

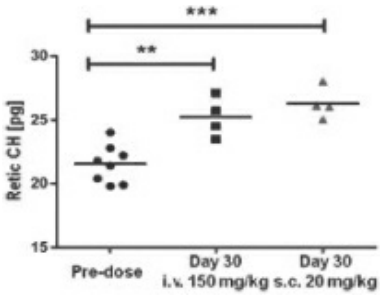


We then studied the functional consequences of hepcidin inhibition on iron mobilization in cynomolgus monkeys. A dose of 1 mg/kg PRS-080 produced a robust, transient and reversible increase in total iron levels from approximately 36 µM at baseline to 52 µM after 8 hours. Doses higher than 1 mg/kg elevated serum iron concentrations to comparable levels and, in a dose-dependent manner, prolonged the response. A linear correlation was observed over time between the PRS-080 dose and increase of serum iron concentrations.

The below chart shows the increase in serum iron concentrations in cynomolgus monkeys following a single intravenous administration of PRS-080 at 10 mg/kg compared to wild-type NGAL administered at the same dose:



The functional consequence of PRS-080 treatment on bone marrow activity and red blood cell production, or hematopoiesis, by means of hemoglobin, an oxygen transporting protein contained in red blood cells) concentration in reticulocytes, a precursor of red blood cells, was investigated in cynomolgus monkeys following repeated administration. As shown in the below chart, after administration of PRS-080 either intravenously (i.v. 150 mg/kg, **) or subcutaneously (s.c. 20 mg/kg, ***), elevated hemoglobin concentrations in reticulocytes (Retic CH) were observed on day 30 compared to pre-treatment (pre-dose).



The PK properties of PRS-080 were investigated in cynomolgus monkeys after a single administration at doses ranging from 20 mg/kg to 150 mg/kg. The concentration over time profiles of PRS-080 showed standard drug-like properties, as the kinetics were dose proportional and there was a low volume of distribution. Elimination of PRS-080 occurred with a terminal half-life of about 2 days which can be extrapolated to translate to 3 days in humans.

PRS-080 administration to cynomolgus monkeys was well tolerated up to the highest tested dose of 120 mg/kg. This dose was classified as producing no adverse events, routine laboratory tests and blood cell examinations did not demonstrate any adverse findings and safety pharmacology investigations were without adverse events. As a result of the hepcidin inhibition, the study showed increased iron uptake and storage, for example in the liver, and mobilization.

Phase I trial design and results

The Phase Ia trial of PRS-080 was conducted in healthy volunteers at a clinical site in Neu-Ulm, Germany by Nuvison GmbH, a CRO. The study was a single dose escalating, blinded, placebo controlled study at a dose range from 0.2 to 40 mg/kg (equivalent to 0.08 to 16.0 mg/kg based on protein content). Forty-eight subjects were dosed with PRS-080 or a placebo. This study was governed and approved by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) and the local Ethics Committee. Treatment of subjects began at the end of 2014 and was completed in June 2015, followed by evaluation of the data.

PRS-080 was well tolerated. All treatment emergent Adverse Events, or AEs, were either mild or moderate and no Serious AEs were observed. No association of AEs to specific organs and no apparent dose dependency or difference between placebo and active treatment was observed. Notably, no hypersensitivity or infusion reactions were noted and vital signs, body temperature and electrocardiograms were unchanged. Pharmacokinetics of PRS were dose-proportional with a half-life of approximately 3 days. PRS-080 administration resulted in an immediate decrease in plasma hepcidin concentration which was followed by an increase in serum iron concentration and transferrin saturation. The duration of this response in iron and transferrin saturation increased dose-dependently from about 18 hours at the lower dose to about 120 hours at the highest dose.

Based on this positive safety and pharmacological activity we are advancing PRS-080 in a Phase lb study in CKD patients suffering from FID-anemia. We first plan to enroll CKD patients to study pharmacokinetics in a

single-dose format. We plan to subsequently dose repeatedly and study the effects of PRS-080 administration on iron mobilization and hemoglobin levels in CKD patients.

PRS-060 targeting IL-4RA in asthma

PRS-060 is an Anticalin® drug candidate targeting IL-4RA, a cell surface receptor expressed on immune cells in the lung epithelium and mucosal layer. IL-4RA is specific to the circulating cytokines IL-4 and the closely related cytokine IL-13, both key drivers of the immune system that induce differentiation of naïve helper T cells to type 2 helper T cells, or Th2. PRS-060 is derived from human tear lipocalin, has picomolar affinity for human IL-4RA (20 pM) and has a favorable stability profile. We showed *in vitro* that PRS-060 can inhibit the activity of both IL-4 and IL-13. We have formulated PRS-060 for pulmonary delivery by inhalation, and we are actively preparing to carry out bioprocess optimization in preparation for cGMP, manufacturing and preclinical safety and tolerability studies. Pending the results of our preclinical studies, we intend to pursue a first-in-human clinical trial for PRS-060 in 2017. Some of the development of PRS-060 is conducted in Australia, where we intend to access leading pulmonologists for potential patient recruitment and to seek up to 40% or more in tax refunds from the Australian government in connection with research and development expenses related to PRS-060. We believe PRS-060 represents a first-in-class inhaled biologic for the treatment of asthma.

Asthma market

Asthma is a very common chronic airway disorder affecting approximately 300 million people worldwide according to the Global Initiative for Asthma and approximately 26 million Americans according to the U.S. Centers for Disease Control. Of these 26 million, about 7 million are children. Asthma is responsible for 13 million physician visits a year including about 2 million emergency visits in the United States, according to the American Lung Association. In 2007 asthma was responsible for $50 billion in direct healthcare costs each year in the United States (Barnett and Nurmagambetov, 2011, Journal of Allergy and Clinical Immunology, Volume 127, pp145-152).

Challenges in using conventional therapy

According to a 2012 Artisan Health Care Consulting analysis, as of 2011 asthma affects approximately 195 million people in the U.S., Europe, Japan, Brazil, Russia, India and China. The analysis determined that approximately 16%, or 32 million, of the group studied were considered to have moderate and severe uncontrolled asthma, while approximately 60%, or 19 million, of the group of moderate and severe uncontrolled asthma studied were considered to have moderate and severe uncontrolled asthma with an elevated Th2 signature. Inflammation brought about by Th2 immunity is addressed by standard asthma therapies. 5-10% of patients with asthma have moderate to severe disease that is not controlled with standard of care therapies.

The current standard of care for persistent, moderate to severe allergic asthma is omalizumab (Xolair from Roche) which is given in conjunction with high dose inhaled corticosteroids often in combination with inhaled long-acting beta adrenergic agonists, or LABA. Omalizumab was approved for this condition in the United States in 2003. Outside of the United States, omalizumab is approved for severe asthma. Omalizumab works by binding to the immune mediator immunoglobulin E, or IgE, and inhibiting IgE-mediated activation of mast cells and basophils, types of white blood cells. It has also been shown to impact some diseases, such as asthma, that are driven by eosinophils, another important class of immune cells. However, patient response to omalizumab has been shown to be inconsistent, as reported in a publication by McNicholl and Heaney in 2008 in the journal *Core Evidence*, which explained that in only some studies did omalizumab improve lung function. Furthermore, general asthma symptoms are also typically unaffected by omalizumab. Finally, in 2007, the U.S. Food and Drug Administration, or the FDA, issued a black box warning for omalizumab due to reported cases of anaphylaxis, a potentially life-threatening allergic reaction suffered by some patients who had taken the drug. Despite these shortcomings, in 2012, worldwide sales of omalizumab were reported by Roche to be $1.2 billion.

The next generation of therapies beyond omalizumab targets a broader range than just IgE mediated mechanisms. These approaches target other immune mediators, including IL-5, IL-4 and IL-13 (which act in concert on eosinophils, B-cells, epithelial cells, goblet cells and others) and CRTH2. Asthma is associated with high levels of eosinophils, immune cells that play a role in protecting the body against infection. The creation of eosinophils can be interrupted at the early stages, while the cells are still maturing. Multiple products are in development that target eosinophils and GlaxoSmithKline's, or GSK, mepolizumab which targets IL-5 was approved for severe eosinophilic asthma in adults and children older than 12 in 2015. However, eosinophils are only one of many cell types and immune system components that are involved with the body's exaggerated inflammation response in asthma. Mast cells, basophils, goblet cells and other cells also play a role. These cells can be seen infiltrating the airways along with eosinophils, leading to the conclusion that more cell types are involved. We believe that targeting just one of these components is not likely to be as effective in resolving severe asthma as an approach that targets the broader Th2 (cell-mediated) pathway.

In 2013, Regeneron and its partner Sanofi reported proof-of-concept in a Phase IIa trial in persistent asthma with dupilumab, a currently unapproved monoclonal antibody that targets IL-4RA now in clinical development as a subcutaneously delivered agent. In a 2013 paper in the New England Journal of Medicine, Wenzel et al. reported that dupilumab showed a benefit on the asthma control questionnaire 5 (ACQ5) symptom score, a widely accepted measure for classifying the ability of a medication to control asthma. Patients dosed with dupilumab had fewer asthma attacks compared to placebo-treated patients when standard therapies, such as long-acting beta-agonists and inhaled glucocorticoids, were withdrawn, demonstrating the efficacy of dupilumab. Patients also showed improved lung function and reduced levels of Th2-associated inflammatory markers. Dupilumab is administered systemically through injection. In November 2014, Regeneron and Sanofi announced that in a Phase IIb study, dupilumab also demonstrated improved lung function and reduced exacerbations when administered together with standard of care. These effects were observed in both unselected severe asthma patients and selected patients presenting elevated Th2 responses. We believe the results support the possibility of treating persistent uncontrolled asthma with a biologic therapy without narrowing the patient population based on the Th2 phenotype. Dupilumab is currently undergoing Phase 3 clinical trials for severe asthma.

Another biologic in development for severe asthma is lebrikizumab, which blocks IL-13, a mechanism known to have a similar effect to that of dupilumab. Like dupilumab and other mediators of the Th2 pathway, lebrikizumab is a validating example for subcutaneously delivered Th2 intervention in treating uncontrolled asthmatics. In a 2011 publication in the New England Journal of Medicine, lebrikizumab was reported to improve lung function in severe asthma patients who were also receiving standard of care inhaled glucocorticoid therapy. At the same time, patients in the study who received lebrikizumab showed greater musculoskeletal side effects than patients receiving placebo. We believe that the ability to impact disease biology and improve lung function with biologics such as lebrikizumab is a promising result.

We believe that there could also be significant advantages to other routes of administration, such as inhalation, of biologics that target asthma through the Th2 pathway. If delivered by inhalation, such biologics could be dosed at much lower levels and may preferentially direct the therapy to the site of the disease, in this case the lung.

Our proposed solution: binding IL-4RA with PRS-060

We propose to take PRS-060 forward into clinical trials first in healthy volunteers and then in severe asthma patients. These trials could accomplish two important goals: we could establish proof-of-concept for inhaled Anticalin® proteins, opening up a second route of administration for our drug candidates beyond intravenous or subcutaneous injection. Following the demonstration that inhaled PRS-060 is well tolerated in healthy volunteers, we plan to enter a proof-of-concept trial in these patients, where we will evaluate whether PRS-060 can improve patient symptoms. We intend to begin a Phase I clinical trial for PRS-060 in 2017.

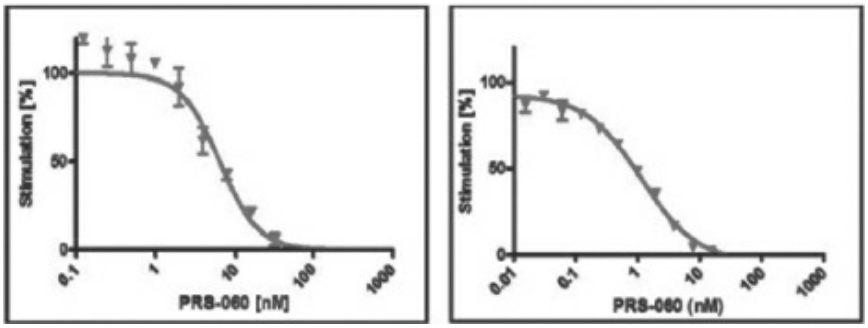
Advantages to inhalation as a route of administration for PRS-060

We have performed inhalation studies in mice and observed that systemic concentrations of PRS-060 are minimal when dosed by inhalation, as a result of low doses and short systemic residence time. This offers the

potential of a wider therapeutic window and possibly lower systemic side effects that may become prevalent with chronic, systemic Th2 targeting. By our calculations, the total annual dose of PRS-060 can be significantly lower than the doses being used for the monoclonal antibodies dupilumab and lebrikizumab. Furthermore, we believe that PRS-060 can be produced at a lower cost of goods than monoclonal antibodies because we intend to use manufacturing procedures that employ bacterial expression systems, which generally provides a cost advantage over mammalian production systems, typically used for mAbs. Since dosing by inhalation is a common route of administration in asthma patients, it represents a more convenient dosage regimen for patients than dosing of antibodies by injection and would not need to be administered in a physician's office or other medical setting.

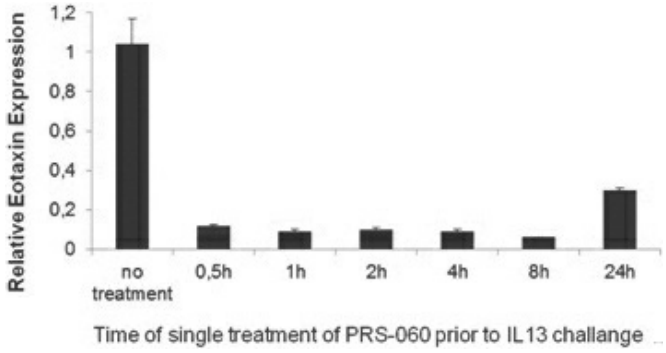
Preclinical data

In *in vitro* assays, PRS-060 specifically bound to immobilized targets such as human IL-4RA in a concentration-dependent manner. We tested the binding of PRS-060 to various targets in enzyme-linked immunosorbent assay, or the ELISA, a standard *in vitro* assay platform. In these tests, PRS-060 bound to IL-4RA with subnanomolar affinity and it did not bind to three other human cell-surface interleukin receptors (IL-6R, IL-18RA, IL-23RA). Furthermore, the activity of IL-4 and IL-13 was inhibited by PRS-060 in a dose-dependent manner. The below charts below show the inhibition of IL-4 (left) or IL-13 (right) induced proliferation in human TF-1 cells *in vitro* by PRS-060.



In *in vivo* assays in mice genetically altered to express human IL-4RA and IL-13R, low doses of PRS-060 inhibited the induction of eotaxin protein, a marker or airway inflammation, in lung tissue following pulmonary delivery. We observed this inhibition at both the RNA and protein levels compared both to buffer and to tear lipocalin.

The below chart shows the duration of PRS-060-mediated inhibition of eotaxin gene expression, a marker of airway inflammation, in lung tissue by a single pulmonary dose in mice:



When we administered IL-13 into the lung, inflammation was induced as determined by eotaxin expression, which was not inhibited when phosphate buffered saline, or PBS, or human Wild Type lipocalin was administered into the lung. In contrast to the PBS administration, eotaxin expression and, as a result, inflammation was prevented when PRS-060 was administered into the lung before IL-13. As demonstrated in the above chart, the model showed the inhibitory potential lasts for up to 24 hours after PRS-060 administration.

PRS-343 targeting CD-137 in oncology

PRS-343 is a bispecific protein targeting the immune receptor CD137 and the tumor target HER2. It is generated by genetic fusion of an Anticalin specific for CD137 with a variant of the HER2-targeting antibody trastuzumab. The mode of action of this CD137/HER2 bispecific is to promote CD137 clustering by bridging CD137-positive T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells. PRS-343 is intended to localize CD137 activation in the tumor, and to thereby both increase efficacy and reduce systemic toxicity compared to CD137-targeting antibodies being developed by third parties in clinical trials.

Biology of the costimulatory immune receptor CD137

CD137, also known as 4-1BB, is a co-stimulatory immune receptor and a member of the tumor necrosis factor receptor, or TNFR, super-family. It is mainly expressed on activated CD4+ and CD8+ T cells, activated B cells, and natural killer, or NK, cells. CD137 plays an important role in the regulation of immune responses and thus is a target for cancer immunotherapy. CD137 ligand (CD137L) is the only known natural ligand of CD137, and is constitutively expressed on several types of antigen-presenting cells, or APC. CD137-positive T cells are activated by engaging a CD137L-positive cell. The induced CD137 clustering leads to activation of the receptor and downstream signaling. Note that the trimeric CD137L as a soluble molecule is not an effective CD137 agonist, providing evidence that larger scale clustering is required for activation. In a T cell pre-stimulated by the T cell receptor binding to a cognate Major histocompatibility complex, or MHC, target, costimulation via CD137 leads to further enhanced activation, survival and proliferation, as well as the production of pro-inflammatory cytokines and an improved capacity to kill.

Validation of CD137 as a therapeutic target in cancer

The benefit of CD137 costimulation for the elimination of cancerous tumors has been demonstrated in a number of in vivo models in the mouse. The forced expression of CD137L on a tumor, for example, leads to tumor rejection. Likewise, the forced expression of an anti-CD137 single chain antibody fragment (scFv) on a tumor leads to a CD4+ T-cell and NK-cell dependent elimination of the tumor. A systemically administered anti-CD137 antibody has also been demonstrated to lead to retardation of tumor growth.

Human ex vivo data supports the extraordinary potential of CD137 as a costimulatory receptor in cancer therapy: It has been reported that for T cells isolated from human tumors, CD137 is an excellent marker for those that are tumor-reactive. In line with this observation, anti-CD137 antibodies can be utilized to improve adoptive T-cell therapy (ACT) by augmenting the expansion and activity of CD8+ melanoma tumor-infiltrating lymphocytes.

Finally, the potential of CD137 targeting has also been shown in nonclinical combination therapy studies, where an additional benefit was demonstrated by combination of CD137 agonism with checkpoint blockade or NK cell-targeting antibodies.

Current approaches to clinical CD137 targeting

The preclinical demonstration of the potential therapeutic benefit of CD137 costimulation has spurred the development of therapeutic antibodies targeting CD137, PF-05082566 (22, 23) and BMS-663513 which are currently in early phase clinical trials.

PF-05082566 is a fully humanized IgG2 monoclonal antibody that binds CD137 in a manner that blocks the binding of endogenous CD137L to CD137, and that according to publicly available data is well tolerated as a monotherapy and in combination with rituximab.

BMS-663513 is an IgG4 monoclonal antibody that, in contrast to PF-05082566, binds CD137 in a manner that does not interfere with the CD137 / CD137L interaction. While an initial trial reported manageable toxicity with doses up to 10mg/kg, a follow-up monotherapy phase II trial was reported to have been stopped due to an “unusually high incidence of grade 4 hepatitis”. Current clinical trials with BMS-663513 are focusing on safety and efficacy at lower doses as monotherapy or in combination e.g. with Rituximab (NCT01775631).

Rationale for bispecific targeting of CD137

In line with the natural mode of activation of CD137, which requires receptor clustering, an ideal CD137-targeting agent should firstly lead to clustering of CD137, and secondly do so in a tumor-localized fashion on tumor-infiltrating lymphocytes (TIL). The antibodies currently in clinical development are not ideal in that respect, as CD137 clustering can only be induced by binding to Fcg receptor-positive cells which are not selectively tumor-localized but distributed throughout the body for Fcg-dependence of TNFR targeting). The toxicity data of BMS-663513 indicates that such a non-selective activation leads to unacceptable toxicity, potentially making it impossible to find a therapeutic window for such CD137-targeting antibodies.

We therefore hypothesized that to obtain an ideal CD137-targeting agent, a bispecific molecule should be designed that targets CD137 on one end and a differentially expressed tumor target on the other end. A visualization of the general concept is provided in Figure 1, below.HER2/CD137 bispecific is envisioned to promote CD137 clustering by bridging T cells with HER2-positive tumor cells, and to thereby provide a potent costimulatory signal to tumor antigen-specific T cells, further enhancing its T cell receptor, or TCR,-mediated activity and leading to tumor destruction.

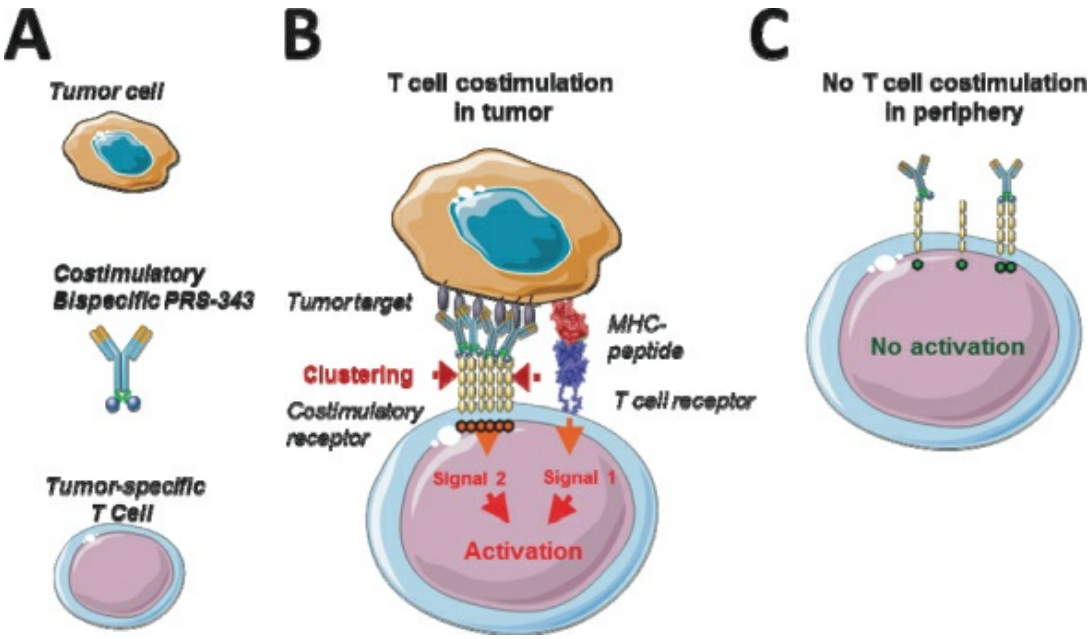


Figure 1 Concept of costimulatory T cell engagement. (A) The elements of the system are a target-positive tumor cell, a T cell with a TCR that is specific for an HLA/peptide combination on the tumor, and a

costimulatory bispecific. (B) Within a patient´s tumor, tumor-specific T cells are bridged with tumor cells by a costimulatory bispecific. The resulting clustering of the costimulatory T cell receptor provides a local co-activating signal to the T cell, further enhancing its TCR-mediated activity and leading to tumor destruction. (C) Toxic side effects are expected to be manageable, as target-negative cells do not lead to costimulation of T cells due to a lack of target-mediated receptor clustering, and healthy tissue is spared by tumor-costimulated T cells due to the absence of a primary, TCR-mediated signal. *Design and Generation of HER2/CD137 bispecific PRS-343*

To obtain a molecule that would work by the mode of action of costimulatory T cell engagement, we generated the HER2/CD137 bispecific PRS-343. The molecule consists of two different building blocks binding to the two targets HER2 and CD137. To generate the CD137-specific building block of PRS-343, termed S0575.04J10, we utilized anticalin technology®. This technology works by engineering lipocalins to bind any desired target protein with high affinity and specificity, in a manner very similar to antibodies. The lipocalin family comprises a diverse group of mostly secreted soluble proteins that bind, store and transport a broad spectrum of molecules, ranging from small molecules to proteins. Lipocalins are structurally related by possessing an 8-stranded beta-barrel structure. Lipocalin-2, also known as neutrophil gelatinase-associated lipocalin, or NGAL, is a component of granules in neutrophils and is up-regulated during inflammation. The primary function of NGAL appears to be the sequestering of bacterial siderophores (iron chelators), leading to an inhibition of bacterial growth. A CD137-binding anticalin was generated based on a re-design of the natural binding pocket of NGAL using mutant anticalin libraries and a selection and screening process. The CD137-binding anticalin S0575.04J10 binds human CD137 with an affinity of 2 nM as determined by SPR, and is capable of costimulating human T cells when immobilized on a plastic dish together with an anti-CD3 antibody.

To generate the HER2/CD137 bispecific PRS-343, we constructed a genetic fusion of the CD137-specific anticalin S0575.04J10 to the C-terminus of the heavy chain of the trastuzumab IgG4 variant, connected by a flexible, non-immunogenic linker sequence of 15 amino acids length.

We utilized a Sandwich ELISA experiment to investigate whether PRS-343 can bind both targets at the same time, which is a necessary prerequisite for the envisioned mode of action of PRS-343. Figure below shows that a sigmoid binding curve results from this titration, proving that both targets can indeed be engaged at the same time, fulfilling the key requirement for simultaneous costimulatory engagement of T cells by HER2-positive target cells.

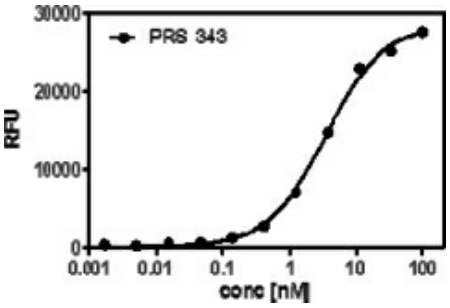


Figure 2 PRS-343 simultaneous binding to targets HER2 and CD137. Recombinant Her2 was coated on a microtiter plate, followed by titration of PRS-343. Subsequently, a constant concentration of biotinylated human CD137 was added, which was detected via a peroxidase-conjugated avidin variant, ExtrAvidin®.

Mode of action – costimulatory T cell activation

We developed a novel T cell activation assay format to investigate whether PRS-343 is capable of costimulating T cells that have received a basic stimulus via the TCR. The assay, visualized in Figure 3 below, is based upon providing the T cell receptor stimulus via an anti-CD3 antibody coated onto the plastic culture dish, while CD137 costimulation is achieved by tumor-target dependent clustering of CD137 on purified T cells.

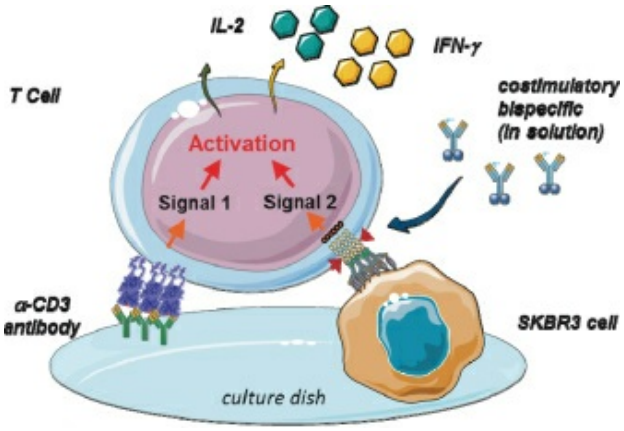


Figure 3 Visualization of costimulatory T cell activation assay. HER2-positive tumor cells are grown overnight on cell culture plates that have been precoated with low amounts of an anti-CD3 antibody to provide a limited primary activation of T cells via the T cell receptor**.** T cells are added to the wells together with *the titrated CD137/HER2 bispecific PRS-343, leading to clustering of the costimulatory CD137 receptor, which in turn results in T cell costimulation. T cell costimulation is detected by increased supernatant IL-2 and IFN-*g *levels in the culture supernatants after continued culture.*

There is a clear induction of IL-2 (Figure A) and IFN-g (Figure C) with increasing concentrations of PRS-343. The fitted EC50 of this effect is similar for both proinflammatory cytokines, with 0.7 nM for IL-2 induction and 0.3 nM for IFN-g induction, respectively. That T cell costimulation is indeed due to the bispecific engagement of T cells and SKBR3 cells is shown by two observations: firstly, the monospecific antibody trastuzumab does not lead to enhanced T cell activation (average shown as dotted line in Figure A and Figure C), and secondly, disrupting the bispecific interaction with an excess of trastuzumab abolishes the effect of IL-2 and INF-g induction nearly completely except at the highest concentrations of PRS-343 employed (Figure B and Figure D).

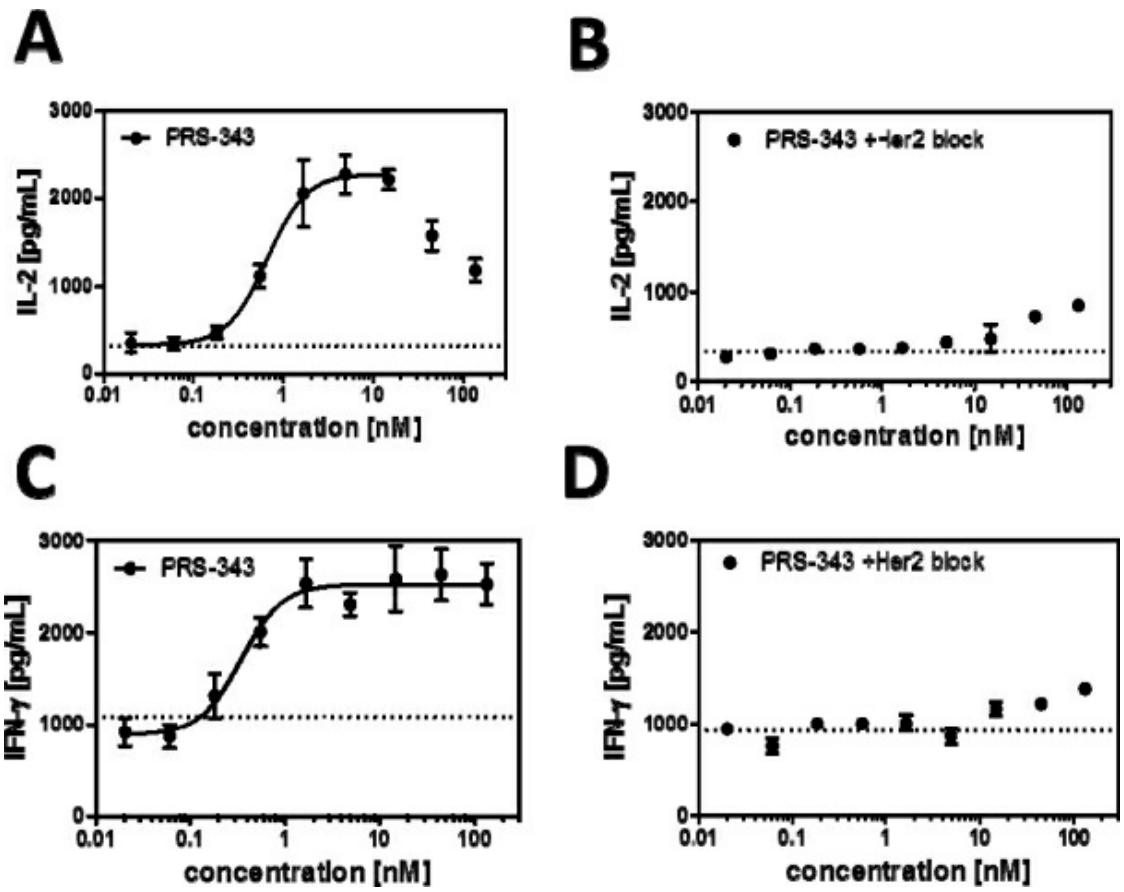


Figure 4 Experimental result of costimulatory T cell activation assay. HER2-positive SKBR3 tumor cells were grown overnight on 96-well plates that had been precoated with 0.25 µg/mL anti-CD3 antibody for 1 h at 37°C. The next day, T cells purified from healthy donor PBMC were added to the wells together with the titrated CD137/HER2 bispecific PRS-343 (filled circle) or trastuzumab as a control (dotted line). After three days in culture, IL-2 (A) and IFN-g,levels in the culture supernatants were measured by an Electrochemoluminescence immunoassay. In parallel, the experiment was performed in the presence of an excess of trastuzumab (340 nM) to inhibit the binding of PRS-343 to the SKBR3 cells, and IL-2 (C) and IFN-g (D) levels were measured.

Pipeline products: 300 Series

Current antibody-based therapies targeting tumor cell destruction or immune activation are hampered by, among other factors, low response rates and the induction of immune-related adverse events. The 300-Series Anticalin® proteins are designed to target checkpoint proteins or, like PRS-343, immune-stimulatory proteins and consist of a variety of multifunctional biotherapeutics that can combine, via a genetic fusion, antibodies with Anticalin proteins or two or more Anticalin proteins to each other. These combined molecules have the potential to build upon current therapies through the capability of modifying or regulating one or more immune functions on a single fusion protein, thereby having the potential to elevate immune responses within a tumor microenvironment. We believe that a tethered Anticalin protein directed at checkpoint proteins can preferentially activate the immune system at the site of the tumor microenvironment thus providing efficacy with enhanced

therapeutic index. We believe that the 300-Series Anticalin proteins represent a “platform within a product” opportunity in immuno-oncology since it may be possible to apply a single combined Anticalin-antibody molecule in a number of different cancers. This is based on the shared underlying biology such as checkpoint and costimulatory biology found within tumors arising in different organs.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience, scientific knowledge and strategies provide us with competitive advantages, we face and will continue to face intense competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, both in the United States and abroad.

We compete, or will compete, with existing and new therapies that may become available in the future. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our drug candidates target. Any drug candidates that we are able to develop and commercialize will compete with existing and new drugs being developed by our competitors. Our competitors may develop or market products or other novel technologies that are more effective, safer, more convenient or less costly than any that may be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive, and a number of more established companies, some of which have acknowledged strategies to license or acquire products and many of which are bigger than us and have more institutional experience and greater cash flows than we have, may have competitive advantages over us, as may other emerging companies taking similar or different approaches to product licenses and/or acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines, which may provide those companies with an even greater competitive advantage.

There are a number of other companies presently working to develop therapies for anemia, asthma and oncology, including divisions of large pharmaceutical companies and biotechnology companies of various sizes. There are also a variety of available drug therapies marketed for these diseases. Our drug candidates, if any are approved, may compete with these existing drug and other therapies, and to the extent they are ultimately used in combination with or as an adjunct to these therapies, our drug candidates may not be competitive with them. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. As a result, market acceptance of, and a significant share of the market for, any of our drug candidates that we successfully introduce to the market will pose challenges.

In addition to currently marketed therapies, there are also a number of medicines in clinical development to treat anemia, asthma or cancer. These medicines in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies and may not be provided by any of our current or future product candidates. As a result, they may provide significant competition for any of our product candidates.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in some of our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build, obtain regulatory approval for and market acceptance of, and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

In addition, our competitors may have a variety of drugs in development or awaiting market approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities; and
- sales and marketing.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved by the FDA or its foreign counterparts or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

PRS-080

Other drug candidates in development that interfere with hepcidin function or expression include ISIS/Xenon (anti-sense) and Alnylam (RNAi), which have nucleic acid based approaches aimed at reducing hepcidin synthesis in preclinical development. Noxxon's RNA aptamer sequesters hepcidin and is in clinical studies in cancer and ESRD patients. A mAb against hepcidin is tested in cancer as well as chronic kidney disease patients by Lilly as well as a mAb against the ferroportin transporter. Ferrumax develops a soluble form of hemojuvelin, a protein that regulates hepcidin expression and iron metabolism that aims to suppress the production rate of hepcidin.

There are also a number of companies which are focused on treating anemia in CKD patients under alternative approaches. Fibrogen, Akebia Therapeutics, GSK, Bayer, and Japan Tobacco have hypoxia-inducible-factor prolyl hydroxylase (HIF-PH) inhibitors in clinical development that target stimulation of bone marrow activity. Acceleron is also targeting the sequestration of Activin A, a natural inhibitor of hematopoiesis, is in a Phase II clinical study. Auryxia by Keryx, which targets formulation of oral iron, completed a Phase III in non-dialysis dependent CKD 3-5 patients recently (January 2016). There are also various companies conducting late-stage development of erythropoietin biosimilars.

PRS-060

Like PRS-060, new developments for the treatment of uncontrolled moderate to severe asthma patients mainly include drug candidates targeting the Th2 pathway by interfering with IL4/IL-13 or IL-5 actions. Such products

include dupilumab (Sanofi/Regeneron, IL-4RA), lebrikizumab (Roche/Genentech, IL-13), tralokinumab (Astra Zeneca, IL-13), mepolizumab (GSK, IL-5), reslizumab (Teva, IL-5), and benralizumab (Astra Zeneca, IL-5R). These drugs are in later clinical development (Phase II and Phase III) than PRS-060, or have been approved (mepolizumab); however, in contrast to PRS-060, these mAbs are given to patients through injection and distribute systemically through the blood stream. There are a number of other companies presently marketing or developing other therapies for asthmatic patients. The mAb omalizumab, directed against IgE, is approved and marketed for the treatment of uncontrolled, moderate to severe asthma patients.

PRS-300 series

Other drug candidates which target checkpoint proteins include ipilimumab, which is specific for the checkpoint protein CTLA-4 and has been marketed by Bristol Myers Squibb for the treatment of melanoma patients since 2011. Additionally, preclinical and/or clinical testing currently focusing on additional checkpoint mechanisms and targets include PD-1 / PD-L1, LAG3, IDO, TIM3, Ox-40, CD-137, CD70, KIR and NKG2A. Bristol Myers Squibb and Roche are most active in this area, with multiple single agent or combination therapy trials ongoing. Merck and AstraZeneca also have active trials ongoing, while Novartis is placing more of an emphasis on adoptive T cell transfer technology in its developmental efforts. In September 2014, Merck received FDA approval for its anti- PD-1 antibody, pembrolizumab, for the treatment of patients with advanced or inoperable melanoma.

Under the 300-Series, we are also developing multispecific molecules to facilitate the more effective activation of the immune system, with a strategy of employing multispecific Anticalin® protein-based molecules that may favorably bias an immune response to the tumor microenvironment. A number of other companies, such as Amgen, Affimed, Macrogenics, F-Star and Sutro, also pursue multispecific approaches in oncology, which therapies are in clinical or preclinical development.

PRS-343

PRS-343 is bispecific anticalin-antibody fusion protein targeting CD137 and HER2. Other drug candidates targeting the co-stimulatory receptor CD137 include urelumab, which is being developed by Bristol Myers Squibb, and PF-05082566, which is being developed by Pfizer, both of which are currently in clinical development (Biomedtracker, January 21, 2016). In the HER2-positive space, several actors are active with approved, clinical and preclinical drugs candidates. The most prominent actor is Roche, having three approved drugs on the market through its subsidiary Genentech. The first drug from Roche targeting HER2 is Trastuzumab, which has been marketed for treatment of breast cancer patients since 1998 and for gastric cancer patients since 2010. The two other drugs are pertuzumab and Ado-trastuzumab Emtansine which both are marketed for breast cancer patients.

No known competitor is developing a CD137 and HER2 bispecific drug candidate but a number of companies such as Amgen, Affimed, Macrogenics, F-Star, Sutro Biopharma and Immunocore are pursuing multispecific approaches in immuno-oncology, which therapies are either approved, in clinical development or preclinical development.

Additionally, other actors such as AstraZeneca, Novartis, Agenus, Five Prime Therapeutics and Celldex have preclinical and clinical development programs focusing on other co-stimulatory targets which include OX40, CD40, GITR and CD27.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party contract manufacturers, or CMOs, for the manufacture of our drug candidates for larger scale preclinical and clinical testing, as well as for commercial quantities of any drug candidates that are approved.

We currently rely on one CMO for all of our clinical supplies, including active pharmaceutical ingredients, or APIs, drug substances and finished drug products for our preclinical research and clinical trials, including the Phase Ia trial for PRS-080.

We believe that we will be able to contract with another CMO to obtain API if our existing source of API was no longer available or sufficient, but there is no assurance that API would be available from another third-party manufacturer on acceptable terms, on the timeframe that our business would require, or at all. We do not have long-term supply commitments or other arrangements in place with our existing CMO. We also do not currently have arrangements in place for redundant supply of bulk drug substance.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our drug candidates if they are approved, and we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of our product candidates as they near potential approval.

Any drug products to be used in clinical trials and any approved product that we may commercialize will need to be manufactured in facilities, and by processes, that comply with the FDA's current good manufacturing practice requirements and comparable requirements of the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors.

We believe that PRS-080, PRS-060 and PRS 343 and our other Anticalin®-branded drug candidates can be manufactured in reliable and reproducible biologic processes from readily available starting materials. PRS-080 and PRS-060 are produced using bacterial expression systems similar to those that have been used in the past for the production of other proteins and which systems are widely used in the industry. PRS-343 is produced using a mammalian expression system similar to those systems which are widely used in the industry for the production of antibodies. We believe that the manufacturing process is amenable to scale-up and will not require unusual or expensive equipment. We expect to continue to develop, on our own or with our collaborators, drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Intellectual Property and Exclusivity

Our commercial success depends in part on our ability to obtain and maintain exclusivity of our proprietary Anticalin®-brand technologies through intellectual property protection for our drug candidates, libraries of different protein scaffolds and consensus sequences and the fundamental Anticalin platform technology, including novel therapeutic and diagnostic discoveries, as well as other proprietary know-how, and to operate without infringing on the intellectual property rights of others.

We seek to protect our exclusive position of Anticalin® technologies by, among other means, prosecuting our own international, U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We established intellectual property protection in relation to our Anticalin technologies in key global markets, including Australia, Brazil, Canada, China, the European Union, Hong Kong, India, Japan, Korea, New Zealand, Russia, Singapore, South Africa and the United States. We believe we have patent exclusivity relating to drug candidates derived from lipocalin proteins that runs until at least 2020 in the United States. We also rely on trade secrets for confidential know-how, which we generally seek to protect through contractual (e.g. confidentiality) obligations with employees and third parties.

We have protected the goodwill of our Company and our drug candidates, created through innovation and development, by putting in place trademark registrations of Pieris® and Anticalin® as well as several defensive registrations.

We currently, and expect that we will continue to, file patent applications and maintain granted patents directed to our key drug candidates in an effort to establish intellectual property positions relating to new compositions of

matter for these drug candidates, as well as novel medical applications of these compounds in the treatment, prevention or diagnosis of various indications. We also intend to seek patent protection, if available, with respect to biomarkers that may contribute to selecting the right patient population for use of any of our drug candidates, or with respect to pharmaceutical formulations that may be useful to produce final medicinal products.

Following the effective date of our Research and Licensing Agreement with Technische Universität München, or TUM (See "—TUM License Agreement"), and as of March 23, 2016, we owned or were the exclusive licensee of a patent portfolio consisting of several issued U.S. patents, and their respective counterparts in a number of foreign jurisdictions, several pending applications under the Patent Cooperation Treaty, multiple pending U.S. patent applications and corresponding pending patent applications in a number of foreign jurisdictions as well as three pending provisional patent applications, as described in further detail below.

In applicable jurisdictions, we will seek patent term extensions for certain of our patents including the patent term adjustment period in the United States. If we obtain marketing approval for our drug candidates in the United States or in certain jurisdictions outside of the United States, we may be eligible for regulatory protection, such as twelve years of data exclusivity for new biological entities in the United States and as mentioned below, up to five years of patent term extension potentially available in the United States under the Hatch-Waxman Act, 8 to 11 years of data and marketing exclusivity potentially available for new drugs in the European Union, up to five years of patent extension in Europe (Supplemental Protection Certificate), and eight years of data exclusivity potentially available in Japan. There can be no assurance that we will qualify for any such regulatory exclusivity, or that any such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies. See "—Government Regulation."

Among the issued patents we own are U.S. patent No. 7,250,297; U.S. patent No. 7,723,476; U.S. patent No. 8,158,753; U.S. patent No. 8,536,307; and their respective counterparts in the European Union, which patents are directed to the basic Anticalin® protein concept and platform technology (i.e. antagonist or agonist compounds derived from a natural lipocalin protein) and are expected to expire in 2018, subject to patent term adjustments in the U.S. of up to 794 days. In addition, we hold issued U.S. patents Nos.: 7,001,882; 7,118,915; 7,691,970; 7,585,940; 7,893,208; and 8,313,924; and their respective counterparts in a number of foreign jurisdictions, which patents are related to libraries of different scaffolds and consensus sequences such as human apolipoprotein D, human neutrophil gelatinase-associated lipocalin, or hNGAL, and human tear lipocalin, and are expected to expire between 2020 and 2027, subject to patent term adjustments in the U.S. of up to 685 days. We also own U.S. patent No. 7,892,827, which is directed to muteins derived from hNGAL having binding specificity for the cytotoxic T lymphocyte-associated antigen, or CTLA-4, and is expected to expire in 2025, subject to a 350-day patent term adjustments in the U.S., and U.S. patent No. 8,313,924, which is directed to muteins of human tear lipocalin having detectable binding affinity to interleukin 4 receptor alpha chain, or IL-4 receptor alpha, and is expected to expire in 2027, subject to a 424 day patent term adjustment in the United States, as well as their counterparts in the European Union and in a number of foreign jurisdictions.

As a result of research efforts to date under the Research and License Agreement with TUM, we hold a worldwide exclusive license to multiple patents and patent applications. In the United States, we hold an exclusive license to an issued U.S. patent No. 8,598,317 for the composition of matter of mutein of human tear lipocalin binding to the extracellular region of the T-cell co-receptor CD4 with detectable affinity, which patent will expire in 2027 (subject to a patent term adjustment period which is expected to be at least 742 days), as well as to its counterpart in the European Union. We also hold an exclusive license to an issued U.S. patent No. 8,420,051 directed to library of hNGAL scaffold of certain consensus sequence, which patent is expected to expire in 2029 (subject to a patent term adjustment period of 109 days), as well as to its counterparts in the European Union and in a number of foreign jurisdictions. Moreover, we hold an exclusive license to an issued U.S. patent No. 8,987,415 claiming isolated crystalline form of monomeric bacterial lipocalin.

As of March 23, 2016, a significant portion of our pending U.S. patent applications and pending patent applications in foreign jurisdictions was directed to newly-discovered or improved scaffold libraries of lipocalin

muteins, compounds derived therefrom, or the uses of such compounds to treat, prevent and mitigate certain diseases and conditions whose pathological development involve the targets of interest as well as to diagnose, prognose and select treatments for the diseases and conditions. We would expect that any patents that may issue from the pending U.S. patent applications would likely expire between 2029 and 2035 without taking into account possible patent term adjustments or other extensions, however, any and all of these patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term. Specifically, granted patents and pending patent applications directed to Anticalin® proteins for the cMet target currently have terms which could expire as late as 2029, and granted patents and pending patent applications directed to Anticalin proteins for each of hepcidin and IL-4RA currently have terms which could expire as late as 2031. We are actively pursuing intellectual property protection for our 300-Series in key global markets that, if granted, could expire as late as 2035. To date, we are not aware of any third party intellectual property for freedom to operate on our platforms or therapeutic programs.

In addition to patents, we hold three trademarks in the United States, for Anticalin®, Pieris®, and Pocket Binding ®. Similarly, we hold their respective counterparts, either as registered trademarks or as pending applications, in a number of foreign jurisdictions. We expect that we will continue to look for trademark protection for the goodwill associated with our Company and our drug candidates in the countries or regions where we will have investment, research and development, sales or other activities.

We also rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive advantage. We strive to protect our proprietary information, in part, by using confidentiality agreements and/or invention assignment agreements with our collaborators, scientific advisors, employees and consultants. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third-party. We also actively manage our publication and patent applications in that we only disclose information necessary to stir scientific interest or demonstrate patentability without materially compromising the secrecy of our valuable trade secrets and know-how. While we consider trade secrets and know-how to be a critical component of our intellectual property, trade secrets and know-how can be difficult to protect. In particular, with respect to our technology platform, we anticipate that these trade secrets and know-how will over the course of time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel skilled in the technology from academic to industry positions and vice versa. As a result, those proprietary trade secrets and know-how may lose their value to us over a period of time, and we may lose any competitive advantage afforded by them as they become public knowledge.

Strategic Partnerships

Since 2007, we have entered into several licensing, research and development collaborations to complement our drug discovery and early stage development capabilities. Specifically, we have entered into licensing, research and development agreements which are still active as of the date hereof with Allergan, Inc., or Allergan, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA) and collectively, Sanofi, Daiichi Sankyo and Roche. Under these licensing and research and development arrangements, we have developed and conducted or will develop and conduct selection and screening of drug candidates as well as *in vitro* potency and efficacy testing using our Anticalin®-brand drug discovery platform, our Anticalin-brand libraries and other proprietary methods to generate, identify and characterize drug candidates against certain biological targets associated with several diseases. These agreements have provided us with approximately €33.4 million ($36.3 million) in revenue to date, excluding grant revenues. With respect to discontinued collaborations, we have no ongoing performance obligations, and do not expect to receive any significant additional consideration pursuant to those agreements.

Pieris's agreements with Allergan, Sanofi, Daiichi Sankyo and Roche are ongoing and, under which, our partners are obligated to use commercially reasonable efforts to develop and commercialize drug candidates identified in the course of the collaboration. We are entitled to receive from our partners' research, development and

regulatory milestone payments and, in the case of the Sanofi, Daiichi Sankyo and Roche collaborations, royalties on net sales for products developed and commercialized under these collaborations. Under our collaboration with Roche we have received an upfront-payment in January 2016. We plan to continue to actively seek out additional collaboration partners.

In addition to Pieris's agreements with Allergan, Sanofi, Daiichi Sankyo and Roche, we are partnering with companies with expertise in clinical development, regulatory affairs and biologics manufacturing to advance our pipeline products through clinical trials and to market those products. In 2013, Pieris entered into a co-development alliance with Cadila Healthcare Limited, or Zydus, with respect to the development and sale of certain proprietary products, under which Zydus will focus on developing markets and we will focus on developed markets. Pieris has also entered into a joint development and license agreement with Stelis, establishing a collaboration for clinical development and commercialization of certain of our proprietary products, focusing initially on use in ophthalmological applications.

Certain terms and conditions of our active agreements with Allergan, Sanofi, Daiichi Sankyo and Roche are summarized below as well as certain terms and conditions of our co-development agreements with Zydus and Stelis.

Our agreement with Allergan

In August 2009, we entered into an agreement with Allergan, Inc. (NYSE: AGN) for the use of our proprietary Anticalin® technologies in the discovery and development of drug candidates which inhibit a selected target. Under the terms of the agreement, we provided drug candidates for the treatment of ocular diseases, and Allergan is responsible for the further development and commercialization of products based on those candidates and bearing related costs. We have granted Allergan a worldwide and exclusive license under our patent portfolio for the use of certain drug candidates for the treatment and prevention of ocular diseases.

Upon entering into the agreement, we received a payment of $10 million. We are entitled to receive up to an aggregate of $13 million in additional payments on achieving various milestones. We are not entitled to any royalties from sales of products commercialized under our agreement with Allergan. During the term of the agreement and as long as Allergan commercializes the drug candidates designated under the agreement, we may not grant rights to any third party with respect to any drug candidates that inhibit the same target within the field licensed to Allergan.

The agreement will remain in effect until the expiration of the payment obligations of Allergan to us thereunder. Either we or Allergan may terminate the agreement in the event of the other party's material breach of the agreement remains uncured for a specified period or in the event the bankruptcy of the other party. Allergan has the unilateral right to terminate the agreement upon specified prior written notice to us. On termination, all rights granted to Allergan in our Anticalin® technologies would end.

Our collaboration with Sanofi

In September 2010, we entered into a collaboration and license agreement with Sanofi, which was subsequently amended in February 2013. Under the terms of the agreement, we have agreed to use our proprietary Anticalin® technologies to identify drug candidates against certain targets, with further development and commercialization activities conducted by Sanofi. The collaboration started with two targets under two separate collaboration projects and was extended by an additional multispecific Anticalin program in 2013. When we entered the collaboration we granted Sanofi an exclusive worldwide license to develop drug candidates identified in the course of the collaboration and market products based on those drug candidates under the collaboration.

In consideration of our obligations, as a part of the collaboration we received a €3.5 million ($3.8 million) upfront payment and specified research funding. We also are entitled to receive payments on the achievement of

research, development and commercial milestones for each product, with up to €26.0 million ($28.4 million) in development milestones and up to €18 million ($19.6 million) in commercial milestones for the first therapeutic application and lesser amounts on subsequent therapeutic applications. We have the ability to receive over €50 million ($54.5 million) potential milestone payments from the active collaboration project, including estimated milestone payments in connection with one or more subsequent applications. Payments due to us also include tiered mid-to mid-high single digit royalties on sales of products. We have agreed that we will not use our Anticalin® technologies to perform, on our own behalf or for third parties, any research or development activities on the same target to which any active program relates. Unless earlier terminated, the agreement will remain in effect until the expiration of all payment and related obligations of Sanofi thereunder.

During the term of the agreement, Sanofi may terminate any or all programs thereunder for convenience by giving specified prior written notice to us. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach or for the other party's insolvency. If a program or the agreement is terminated by Sanofi, rights in products and developed technology resulting from the terminated program (including the right to grant sublicenses) revert or are transferred to us. If a program is terminated prior to the development of the product by Sanofi, our right to commercialize that product is royalty-free. Otherwise, we would owe to Sanofi royalties in the single digits as a percentage of net sales on such product sold by us or our licensee, with total royalty payments capped at a certain amount, and with the royalty rate dependent on the maturity of the program at the time of termination. Sanofi has terminated two of the three programs (one program was terminated for internal strategic reasons and the other program was terminated following *in vivo* studies, as *in vitro* functionality did not fully translate into *in vivo* functionality for this first in class program), and we have the right to develop and commercialize drug candidates of the terminated programs on a royalty-free basis. The remaining active collaboration project was handed over to Sanofi for further development in the fourth quarter of 2014. Additionally, in January 2015, Pieris transferred to Sanofi ownership of the intellectual property of the remaining active collaboration project, including the obligation for payment of expenses of obtaining patents or other registrations of such intellectual property. All other rights and obligations of the parties under the Sanofi collaboration remain unchanged.

Our collaboration with Daiichi Sankyo

In May 2011, we entered into a definitive collaboration research and technology licensing agreement with Daiichi Sankyo, under which we agreed to use our proprietary Anticalin® scaffold technologies to discover novel drug candidates against two targets chosen by Daiichi Sankyo under two separate collaboration projects. Upon achievement of preclinical development milestones for lead drug candidates, Daiichi Sankyo assumes responsibility for, and to use commercially reasonable efforts in, the further development and marketing of products based on those candidates. We handed over further development responsibility for the two collaboration projects to Daiichi Sankyo in March 2013 and June 2014, respectively.

We received €7.2 million ($7.9 million) upon signing of the collaboration agreement and received research funding. We are entitled to payment on the achievement of research and development milestones of up to €35.9 million ($39.2 million) for the first prophylactic or therapeutic product, with reduced amounts for achievement of those milestones in additional indications. We are also entitled to payment of commercialization milestones of up to €45 million ($49.1 million) for a prophylactic or therapeutic product. On development and commercialization of a diagnostic product, we are entitled to development and commercialization milestones of up to approximately €0.7 million ($0.8 million). We have the ability to receive up to approximately €200 million ($218 million) in potential milestone payments from the two collaboration projects, including estimated milestone payments in connection with one or more additional indications. Daiichi Sankyo is further obliged to pay to us tiered, mid- to mid-high single digit royalties on sales of products for prophylactic and therapeutic uses and low single digits on sales of products for diagnostic uses. We granted Daiichi Sankyo exclusive license rights worldwide for prophylactic and therapeutic products, and nonexclusive rights for diagnostic uses. During the collaboration, we may not use our Anticalin® technologies in research or commercial activities on the designated targets for our own account or with third parties.

Daiichi Sankyo may terminate any program under the collaboration after a certain research stage for convenience by giving specified prior written notice to us. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach or for the other party's insolvency. If a program is terminated, rights in products and developed technology resulting from the terminated program (including the right to grant sublicenses) revert or are transferred to us. If a program is terminated by us because of a material breach by Daiichi Sankyo, our sale of products resulting from the program is royalty-free. If a program is terminated by us because of Daiichi Sankyo's failure to meet diligence obligations or by Daiichi Sankyo for convenience, we will be required to pay to Daiichi Sankyo royalties on sale of products resulting from the program in the low single digits as a percentage of net sales up to a specified aggregate royalty amount.

Unless earlier terminated, the agreement will remain in effect until (i) the expiration of all payment and related obligations of Daiichi Sankyo thereunder or (ii) upon the decision of Daiichi Sankyo not to develop any drug candidate under the collaboration agreement.

Our collaboration with Zydus

In October 2013, we entered into a development and license agreement with Zydus. Under the terms of the agreement, we collaborate with Zydus in the development of certain Anticalin® drug candidates, including PRS-110, and Zydus takes the lead in advancing those products through preclinical and clinical proof of concept development and is responsible for its expenses relating to that advancement, which include drug manufacturing. Zydus has been granted exclusive rights to commercialize these products in India and several other developing countries. We retain the right to commercialize these products in key developed markets. We and Zydus have cross-licensed our respective rights in new inventions derived during the collaboration for these products in these territories.

Under the terms of the collaboration, we would be entitled to a payment on achievement of a certain development milestone in the Zydus territory, and a low-to mid-single digit royalty on product sales. We would also be entitled to a share of Zydus' revenue from a sublicense of its rights in the product. We are obliged on the occurrence of a product's achieving certain development milestones in our territory to make payments to Zydus, and to pay low-single digit royalties on product sales. We also are obliged to share with Zydus a percentage of our revenue received from out-licensing rights in the product in our territory, which percentage varies based on the stage of development of the product at the time of out-licensing, should we choose to out-license the product. Upon completion of a certain stage of clinical development, either party may choose to discontinue development, in which case the other party would have the right to continue development and its payment obligations to the discontinuing party would be reduced. During the term of the agreement, with respect to PRS-110, we may not sell a product, or enable a third party to sell a product, that is the subject of the collaboration in the Zydus territory for use in the treatment, palliation or prevention of certain diseases in humans. Under the terms of the agreement, we could be required to pay up to an aggregate of $18.0 million in milestone payments to Zydus, and could be entitled to a $1.0 million milestone payment from Zydus.

The agreement will remain in effect until both parties cease to have their respective payment obligations thereunder. Either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach, the other party's insolvency, or where the parties conclude that clinical data do not support further development.

Our collaboration with Stelis

In November 2013, Pieris entered into a joint development and license agreement with Stelis. Under the terms of the agreement, we collaborate with Stelis in the development of certain Anticalin® drug candidates, initially for use in the treatment, palliation or prevention of ophthalmology-related diseases. Under the terms of the agreement, we contribute certain proprietary assets to the development project, and Stelis agrees to establish a production process for preclinical and clinical supplies of product at its expense and to perform and fund certain

preclinical studies and a first-in-human clinical study for each product under joint development at the expense of Stelis. We agreed that upon reaching certain development stages for a product, we and Stelis would discuss the possible formation of a joint venture with approximately equal shareholding between Pieris and Stelis to further develop and commercialize such product worldwide. If a party does not wish to enter into a joint venture, the other party may continue development and commercialization of a product, subject to terms and conditions to be established by a separate agreement.

Unless earlier terminated, the agreement will remain in effect on a product by product basis until the later of (i) the parties entry into the joint venture as discussed above, (ii) upon receipt of written notice of a decision not to enter into the joint venture from the other party, the receiving party timely elects to continue development and commercialization of a product, and (iii) the parties agree in good faith on how to dispose of a project in the event that neither party wishes to enter into the joint venture, provided, however, that the term of any product shall automatically end no later than one year after completion of the first phase I trial for such product unless extended by mutual agreement of the parties. Prior to the formation of the joint venture, either party may also terminate the agreement for a material breach by the other party which remains uncured after specified advance notice of such breach, or for the other party's insolvency.

Our collaboration with Roche

On December 8, 2015 Pieris entered into a Research Collaboration and License Agreement with F.Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., collectively Roche, in cancer immune therapy for the research, development and commercialization of Anticalin-based drug candidates against a predefined, undisclosed target.

Under the terms of the agreement, we received an upfront payment of CHF 6.5 million ($6.5 million) in January 2016 and Roche committed to provide research funding, and we may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid-single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to us could surpass CHF 415 million ($415.7 million), excluding royalties.

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended under certain circumstances. During the research term of the agreement, Roche will fund the work to be performed by us pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

Unless earlier terminated, the term of the agreement continues until no royalty or other payment obligations are or will become due under the agreement. The agreement may be terminated (i) by either party based on insolvency or breach by the other party and such insolvency proceeding is not dismissed or such breach is not cured within 90 days; or (ii) after 15 months from the effective date of the agreement, by Roche as a whole or on a product-by-product and/or country-by-country basis upon 90 days prior written notice before the first commercial sale of a product or upon 180 days prior written notice after the first commercial sale of a product. Roche may also, in its sole discretion, terminate the agreement upon a change of control of Pieris involving a company that develops or commercializes biopharmaceutical products.

TUM License Agreement

On July 4, 2003, we entered into a Research and Licensing agreement with TUM, which was subsequently renewed and amended, on July 26, 2007. The agreement establishes a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin® technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. We provided certain funding for TUM research efforts performed under the agreement. The research phase of this collaboration ended on February 28, 2013.

Under the terms of the agreement TUM assigns to us certain materials and records resulting from the research. We retain rights to inventions made by our employees, and TUM assigns to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees have made a certain inventive contribution. With respect to all other inventions made in the course of the research, TUM grants to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retains rights to practice these inventions for research and teaching purposes.

As a result of research efforts to date under the agreement, we hold a worldwide exclusive license under our license agreement with TUM to multiple patents and patent applications. In the United States, we hold an exclusive license to an issued U.S. patent No. 8,598,317 for the composition of matter of mutein of human tear lipocalin binding to the extracellular region of the T-cell co-receptor CD4 with detectable affinity, which patent will expire in 2027 (subject to a patent term adjustment period which is expected to be at least 742 days), as well as to its counterpart in the European Union. We also hold an exclusive license to an issued U.S. patent No. 8,420,051 directed to library of hNGAL scaffold of certain consensus sequence, which patent is expected to expire in 2029 (subject to a patent term adjustment period of 109 days), as well as to its counterparts in the European Union and in a number of foreign jurisdictions. Moreover, we hold an exclusive license to an issued U.S. patent No. 8,987,415 claiming isolated crystalline form of monomeric bacterial lipocalin. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

As consideration for the assignments and licenses, we are obliged to pay to TUM milestone payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. For each of such proprietary products developed by us, we could be required to pay up to an aggregate of approximately €0.2 million ($0.2 million) in milestone payments to TUM under the agreement.

We also are obliged to pay low single digit royalties, including annual minimum royalties, on sales of such products. Should we grant licenses or sublicenses to those patents to third parties, we are obliged to share a percentage of resulting revenue with TUM, which percentage of resulting revenue is creditable against our annual license payments to TUM. Our payment obligations are reduced by our proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement.

We can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate our rights in patents assigned to us.

Upon initiation of the Phase Ia clinical trial of PRS-080 in November 2014, our obligation to pay TUM a milestone payment of €10,000 ($12,101) pursuant to the terms of the TUM License Agreement was triggered. We have certain reporting obligations to TUM under the TUM License Agreement and will report this trigger to TUM pursuant to the terms of the agreement. Upon issuance of such a report, we will be obligated to pay to TUM such milestone payment. We were also involved in a dispute with TUM, for which arbitration has concluded in 2015, which is described in more detail under “Item 3. Legal Proceedings—Arbitration Proceeding with Technische Universität München.”

Government Regulation

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S. The animal and other non-clinical data

and the results of human clinical trials performed under an Investigational New Drug application, or IND, and under similar foreign applications will become part of the NDA.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase I:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- ***Phase II:*** This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- ***Phase III:*** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the End of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the

applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be 6 months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted in 2012, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent

beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Biologics Price Competition and Innovation Act of 2009

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the Public Health Service Act, or PHSA, to create an abbreviated approval pathway for two types of "generic" biologics—biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

In February 2012, the FDA issued 3 draft guidance documents on biosimilar product development. The draft guidance documents are: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," and "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009." In April 2013, the FDA issued a fourth draft guidance entitled, **"**Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants." The guidance documents provide the FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA received public comments on the draft documents and intends to issue final guidance documents in the future. Nevertheless, the absence of a final guidance document does not prevent a sponsor for seeking licensure of a biosimilar under the BPCIA.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan drug to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post- approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track drug's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a

schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Under FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In June 2013, the FDA published a draft Guidance for Industry entitled, "Expedited Programs for Serious Conditions-Drugs and Biologics" which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. The FDA has already granted this designation to over 30 new drugs and has approved several.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 28-member European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Directive and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the submission and approval of a clinical trial authorization application be obtained in each Member State be obtained before commencing a clinical trial in that Member State.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, in the EU, if any of our products receive marketing approval in the European Economic Area, or EEA which is comprised of the 28 member states of the EU plus Norway, Iceland and Liechtenstein, we expect they will benefit from 8 years of data exclusivity and an additional 2 years of marketing exclusivity. An additional one-year extension of marketing exclusivity is possible if during the data exclusivity period, we obtain an authorization for one or more new therapeutic indications that is deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the EU and prevents biosimilars from relying on the holder of the marketing authorization for the reference biological medicine's pharmacological, toxicological and clinical data for a period of 8 years. After 8 years, a biosimilar product application may be submitted and the sponsoring companies may rely on the marketing authorization holder's data. However, a biosimilar medicine cannot launch until 2 years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or 3 years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the 8 year data exclusivity period.

As in the United States, a sponsor may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government healthcare programs, managed care providers, private health insurers and

other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to by significantly lower.

Employees

As of March 23, 2016, we had 38 full-time employees and 1 part-time employee. Of these 39 employees, 27 are engaged in research and development activities and 12 work in general support and administration. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees for research and development, clinical and regulatory affairs and general and administrative activities over the next few years. We also utilize the services of consultants, clinical research organizations and other third parties on a regular basis.

Available Information

Our internet address is www.pieris.com. Copies of the our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the Investors section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have included our website address in this Annual Report solely as an inactive textual reference.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This Annual Report on Form 10-Kcontains forward-looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business, Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no approved products, and will need to raise additional capital to operate our business.

We are a clinical-stage biopharmaceutical company. To date, we have not generated any product revenue and are not profitable, and have incurred losses since our inception in August 2000. For the years ended December 31, 2015 and 2014 we reported net loss of $14.1 million and $9.8 million, respectively. As of December 31, 2015, we had an accumulated deficit of $79.9 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates and the commercialization of approved products, if any.

We are currently focused primarily on the development of our lead drug candidates, PRS-080, PRS-060 and our 300-series programs, as well as our other programs, which we believe will result in our continued incurrence of significant research, development and other expenses related to those programs. If preclinical studies or the clinical trials for any of our drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our drug candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, or on terms acceptable to us, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Our operations have consumed substantial amounts of cash since inception. We expect to need substantial additional funding to pursue the clinical development of our drug candidates and launch and commercialize any drug candidates for which we receive regulatory approval.

We will require additional capital for the further development and commercialization of our drug candidates and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we advance preclinical development of our 300-Series programs, particularly PRS-343, advance PRS-080 through clinical trials and prepare for a potential Phase I clinical trial of PRS-060. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to regulatory requirements, product manufacturing, marketing, sales and distribution.

Furthermore, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and/or cause us to spend our cash resources faster than we expect.

To date, we have financed our operations through a mix of equity investments from private and public investors, the incurrence of debt, grant funding and revenues from our various collaboration agreements, and we expect to continue to finance our operations through equity investments from public investors for the foreseeable future. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all.

If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our Anticalin®-brand technology or drug candidates and could result in our receipt of only a portion of the revenues associated with the partnered drug.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development for our drug candidates or any future commercialization efforts. Any of these events could significantly harm our business, financial condition and prospects.

Our limited operating history as a clinical stage company may hinder our ability to successfully meet our objectives.

We were formed in August 2000 and, since that time our focus has been on discovery of Anticalin®-brand drug candidates. We are currently conducting clinical development of PRS-080, and are continuing preclinical development of PRS-060 and PRS-343 as well as other drug candidates, and are also exploring additional indications that may be suitable for Anticalin-brand drug therapeutics, primarily immuno-oncology candidates. Our drug candidates are in early stages of development, have not obtained marketing approval, have never generated any revenue from sales and will require extensive testing before commercialization. We have limited operating experience with respect to clinical-stage operations and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. In addition, the early-stage nature of our drug development operations can only provide limited operating results upon which you can evaluate our business and prospects.

Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities:

- developing our drug candidates using unproven technologies;
- undertaking preclinical development and clinical trials as well as formulating and manufacturing products;
- obtaining the human and financial resources necessary to develop, test, manufacture, commercialize and market our drug candidates;
- engaging corporate partners to assist in developing, testing, manufacturing and marketing our drug candidates;
- continuing to build and maintain an intellectual property portfolio covering our technology and our drug candidates;

- satisfying the requirements of clinical trial protocols, including patient enrollment, establishing and demonstrating the clinical safety and efficacy of our drug candidates and obtaining necessary regulatory approvals;
- achieving acceptance and use by the medical community of our drug candidates after they receive regulatory approvals;
- maintaining, growing and managing our internal teams as and to the extent we increase our operations and develop new segments of our business;
- developing and maintaining successful collaboration, strategic and other relationships for the development and commercialization of our drug candidates that receive regulatory approvals with existing and new partners; and
- managing our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical trials, regulatory approvals and commercialization continue to increase.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop drug candidates, raise capital, expand our business or continue our operations.

Our global operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations.

Our business is subject to certain risks associated with doing business globally. One of our growth strategies is to pursue opportunities for our business in several areas of the world, both inside and outside of the United States, Germany and Europe, any or all of which could be adversely affected by the risks set forth below. Accordingly, we face significant operational risks as a result of doing business internationally, such as:

- fluctuations in foreign currency exchange rates;
- potentially adverse tax consequences;
- challenges in providing solutions across a significant distance, in different languages and among different cultures;
- different, complex and changing laws governing intellectual property rights, sometimes affording reduced protection of intellectual property rights in certain countries;
- difficulties in staffing and managing foreign operations, particularly in new geographic locations;
- restrictions imposed by local labor practices and laws on our business and operations;
- rapid changes in government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events;
- compliance with a wide variety of complex foreign laws, treaties and regulations;
- tariffs, trade barriers and other regulatory or contractual limitations on our ability to develop or sell our products in certain foreign markets; and
- becoming subject to the laws, regulations and court systems of multiple jurisdictions.

Our failure to manage the market and operational risks associated with our international operations effectively could limit the future growth of our business and adversely affect our results of operations.

Our international operations pose currency risks, which may adversely affect our operating results and net income.

Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. Our reporting currency is the U.S. dollar, however, 54% of our operating

expenses and all of our revenues come from operations outside of the United States. As such, the financial statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year and (3) stockholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in stockholders' equity.

As we realize upon our strategy to expand internationally, our exposure to currency risks will increase. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies and the U.S. dollar will affect our revenues and expenses and could result in exchange losses in any given reporting period.

We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a different currency other than the U.S. dollar, our functional currency, in particular our arrangements for the purchase of supplies or licensing and collaboration agreements with partners outside of the United States. In such cases we may suffer an exchange loss because we do not currently engage in currency swaps or other currency hedging strategies to address this risk.

Given the volatility of exchange rates, we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations.

If we fail to comply with environmental, health and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of any hazardous materials we use and wastes we produce. The use of these materials in our business could result in contamination or injury, which could cause damage for which we may be responsible but may not have sufficient resources to pay. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations, which we may not be able to afford.

Although we maintain workers' compensation insurance for our operations in Germany to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to us. These current or future laws and regulations may impair our research, development or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could cause our financial condition to suffer.

Health and safety regulations in the United States, Germany, and Australia and in the countries where our technology and potential products are licensed or sold may prevent the sale or use of our technology or products in the future.

We are subject to a variety of regulations regarding worker health and safety in the United States, Germany, Australia and in the countries where our technology and potential products are licensed or sold. Because our technology and potential products may frequently involve the manufacture or use of certain chemical or biological compounds, we are required to certify their safety for industrial use and development in a variety of

countries and contexts. As there has not been sufficient testing to determine the long-term health and environmental risks of all of the materials used in the production of Anticalin® drug candidates and any future products, future regulations may ban the use of our products due to the potential risk they pose to workers or may limit the use of our drug candidates in research and commercial settings. Any such regulations may have a substantial negative impact on our business and revenues, and may cause our business to fail. Because we cannot guarantee the long-term safety of use or exposure to materials used during development or manufacture of our products, we may face liability for health risks or harms caused as a result of developing, manufacturing or other processes that use such materials. Any such claims may have a negative impact on our revenues and may prove substantially disruptive to our business in the future.

In addition, under the European Union regulation on classification, labeling and packaging of substances and mixtures, or CLP, we may be required to publicly disclose the composition of our proprietary products or substances, which may facilitate infringement or avoidance of our intellectual property by third parties and may potentially reduce the margin we are able to charge for our products by allowing competitors to more accurately determine our production costs. Future development of the CLP regulation may have a further negative impact our revenues and a substantial negative impact on our business.

We may be limited in our use of our net operating loss carryforwards.

As of December 31, 2015, we had net operating loss carryforwards of approximately $6.0 million that may be used to reduce our future U.S. federal income tax liabilities, if we become profitable on a federal income tax basis. If unused, these tax loss carryforwards will begin to expire between 2018 and 2035. Our ability to use these loss carryforwards to reduce our future U.S. federal income tax liabilities could also be lost if we were to experience more than a 50% change in ownership within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

As of December 31, 2015, we had net operating loss carryforwards of German corporate income tax of $5.9 million and net operating loss carryforwards of German corporate trade tax of $5.7 million that may be used to reduce our future taxable income in our German jurisdiction. Under current German laws, tax loss carryforwards may only be used to offset any relevant later assessment period (calendar year) $1,090,600 plus 60% of the exceeding taxable income and trade profit of such period. Also, certain transactions, including transfers of shares or interest in the loss holding entity, may result in the partial or total forfeiture of tax losses existing at that date. Partial or total forfeiture of tax losses may further occur in corporate reorganizations of the loss holding entity.

As a result of the ownership change Pieris GmbH experienced from the Acquisition and Private Placement in December 2014, we believe that it is more likely than not that future use of the net operating loss carryforwards that existed prior to the Acquisition may be limited significantly or forfeited entirely. Accordingly, we have written off $33.9 million and $22.9 million of corporate income tax loss carryforwards in the German jurisdiction for the 2015 and 2014 periods, respectively. Trade tax loss carryforwards written off in the German jurisdiction were $33.9 million and $21.6 million for the 2015 and 2014 periods, respectively.

Additional reorganizational or ownership changes could limit the use of our existing net operating loss carryforwards in any of our jurisdictions or cause us to forfeit additional loss carryforwards in the future.

Our business and operations would suffer in the event of system failures, and our operations are vulnerable to interruption by natural disasters, terrorist activity, power loss and other events beyond our control, the occurrence of which could materially harm our business.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access as well as telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material

disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our drug candidates could be delayed.

We are also vulnerable to accidents, electrical blackouts, labor strikes, terrorist activities, war and natural disasters and other events beyond our control, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such events and do not have an applicable recovery plan in place. Except for our operations in Germany, where we have business interruption insurance against losses or damages resulting from fire, we do not carry other business interruption insurance that would compensate us for actual losses from interruptions of our business that may occur, and any losses or damages incurred by us could cause our business to materially suffer.

There could be an adverse change or increase in the laws and/or regulations governing our business.

We are subject to various laws and regulations in different jurisdictions, and the interpretation and enforcement of laws and regulations are subject to change. We are also subject to different tax regulations in each of the jurisdictions where we conduct our business or where our management is located. We expect the scope and extent of regulation in the jurisdictions in which we conduct our business, or where our management is located, as well as regulatory oversight and supervision, to generally continue to increase. There can be no assurance that future regulatory, judicial and legislative changes in any jurisdiction will not have a material adverse effect on us or hinder us in the operation of its business.

Risks Related to the Discovery and Development of Our Drug Candidates

We are heavily dependent on the successful development of our drug candidates and programs and we can not be certain that we will receive regulatory approvals or be able to successfully commercialize our products even if we receive regulatory approvals.

We currently have no products that are approved for commercial sale. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead drug candidates, our 300-Series programs, particularly PRS-343, PRS-080, PRS-060, as well as our other programs. We completed dosing of healthy volunteers in a Phase Ia clinical trial with PRS-080 in June 2015 and PRS-060 is in preclinical development. We are also conducting preclinical experiments on a number of 300-Series lead candidates. All of our other drug candidates are in the discovery or early preclinical stage. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of PRS-080, PRS-060 and our 300-Series programs, which may never occur.

Before we can generate any revenues from sales of our lead drug candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete:

- conduct additional preclinical and clinical development;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval;
- establish manufacturing relationships for the clinical supply of the applicable drug candidate;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- develop and implement marketing strategies; and
- invest significant additional cash in each of the above activities.

Clinical testing of PRS-060 and our 300-Series programs, including PRS-343, has not yet commenced, and the results of any future preclinical studies or clinical trials of PRS-060 and our 300-Series programs, if unsuccessful, could lead to our abandonment of the development of those drug candidates as well. If studies of these drug candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed.

Preclinical and clinical testing of our drug candidates that have been conducted to date or will be conducted in future may not have been or may not be performed in compliance with applicable regulatory requirements, which could lead to increased costs or material delays for their further development.

Given the complexity as well as the uncertainty inherent in biopharmaceutical preclinical studies and clinical trials, and because of our limited operating experience, we may discover that our own development activities have not been or are not in compliance with applicable regulatory requirements or have otherwise been or are deficient, and, therefore, advancement of the development of the drug candidates on the basis of those trials and studies is not warranted or will be delayed.

We have also entered into license and partnership arrangements, such as with Allergan Inc., or Allergan, Daiichi Sankyo Company Limited, or Daiichi Sankyo, Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA), or Sanofi, Cadila Healthcare Limited (Zydus Cadila), or Zydus, Strides Arcolab Limited, or Stelis, and F.Hoffmann—La Roche Ltd., or Roche, relating to certain of our drug candidates, and may continue to do so in the future. Under certain of such arrangements, the development of those drug candidates has been, or in the future may be, conducted wholly by such partners or any third parties with which the partners contract. As a result, we have not been or may not be closely involved with or have any control over those development activities. Although certain of such partners have provided information regarding those drug candidates and the related preclinical studies conducted to date, including certain data that is included in this Annual Report on Form 10-K, we have not received and do not yet have access to comprehensive information regarding those development activities, including the raw data from the studies that have been conducted, information regarding the design, procedural implementation and structure and information regarding the manufacture of the drug candidates used in the studies. Because we have had no input on the development to date of these drug candidates, we may discover that all or certain elements of the trials and studies our partners have performed have not been, or may not in the future be, in compliance with applicable regulatory standards or have otherwise been or may be deficient, and that advancement of the development of these drug candidates on the basis of those trials and studies is not warranted.

Further, the majority of our development activities for each of our drug candidates to date, including our Phase I clinical trial with PRS-080 in healthy volunteers, which was conducted in Germany, have been or are being conducted outside the United States, primarily in Europe as well as in Australia, and we may conduct some of our future development activities in other countries or regions. As a result, although those studies may meet the standards of certain applicable foreign regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable U.S. Food and Drug Administration, or FDA, standards to allow immediate further development of those drug candidates in the United States, and also may not meet the standards of the applicable regulatory authorities in foreign countries in which we desire to pursue marketing approval for these drug candidates.

If the studies conducted by us or our partners or collaborators have not been in full compliance with applicable regulatory requirements or are otherwise not eligible for continued development in the United States, then we or our partners may be forced to conduct new studies in order to progress the development of our drug candidates. We, or our partners, may not have the funding or other resources to conduct or complete these new studies, which would severely delay the development plans for these drug candidates and their commercialization. Any such deficiency and delay in the development of these drug candidates would significantly harm our business plans, product revenues and prospects.

Our research and development is based on a rapidly evolving area of science, and our approach to drug discovery and development is novel and may never lead to marketable products.

Biopharmaceutical product development is generally a highly speculative undertaking and by its nature involves a substantial degree of risk. Our specific line of business, the discovery of Anticalin®-brand drug therapeutics for patients with a variety of diseases and conditions, such as anemia, asthma and cancer, is an emerging field, and the scientific discoveries that form the basis for our efforts to develop drug candidates are relatively new. Further, the scientific evidence to support the feasibility of developing drug candidates based on those discoveries is both preliminary and limited. In contrast with companies who focus on more traditional drug classes, such as antibodies and small molecules, we believe we are the first, if not the only company, to work with Anticalin-brand drug therapeutics and work to advance these to a clinical stage of development. We are not aware of any company that has successfully developed and obtained approval for a drug based on Anticalin proteins. As a result, identifying drug targets based in part on their suitability with Anticalin-brand drug therapeutics, which is a fundamental aspect of our business approach, may not lead to the discovery or development of any drugs that successfully treat patients with the diseases and conditions we intend to target. Moreover, the lack of successful precedents in the development of Anticalin proteins could result in added complexities or delays in our development efforts. The failure of the scientific underpinnings of our business model to produce viable drug candidates would substantially harm our operations and prospects.

We may not be successful in our efforts to build a pipeline of drug candidates.

A key element of our strategy is to use and expand our Anticalin® drug platform to build a pipeline of drug candidates to address different targets, and progress those drug candidates through clinical development for the treatment of a variety of different types of diseases. Although our research efforts to date have resulted in identification of a series of targets, we may not be able to develop drug candidates that are safe and effective inhibitors or promoters of all or any of these targets. Even if we are successful in building a product pipeline, the potential drug candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential drug candidates fail to produce a pipeline of potentially viable drug candidates, then our success as a business will be dependent on the success of fewer potential drug candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, is very difficult to design and implement, and any of our clinical trials could produce unsuccessful results or fail at any stage in the process.

Clinical trials conducted on humans are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Additionally, any positive results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the results of later-stage clinical trials, such that drug candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier phases of the trials. Therefore, the results of any ongoing or future clinical trials we conduct may not be successful.

We completed dosing of healthy volunteers in the clinical Phase Ia trial for PRS-080 in June 2015, and are planning to initiate clinical trials for PRS-060 as early as the first quarter of 2017. We may however experience delays in pursuing those or any other clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner, and may not be completed on schedule, if at all.

Clinical trials may be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- enrolling suitable volunteers or patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- changes in dosing or administration regimens;
- having patients complete a trial or return for post-treatment follow-up;
- inability to monitor patients adequately during or after treatment;
- clinical investigators deviating from trial protocols or dropping out of a trial;
- regulators instituting a clinical hold due to observed safety findings or other reasons;
- adding new or substituting clinical trial sites; and
- manufacturing sufficient quantities of drug candidate for use in clinical trials.

We rely and plan to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have and expect that we will have agreements in place with CROs governing their committed activities and conduct, we will have limited influence over their actual performance. As a result, we ultimately do not and will not have control over a CRO's compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements, or its adherence to agreed time schedules and deadlines, and a future CRO's failure to perform those obligations could subject any of our clinical trials to delays or failure.

Further, we may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or Ethics Committee at an institution in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for the trial, if applicable, or by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

If we experience delays in the commencement or completion of, or suspension or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be harmed, and our ability to generate product revenues from the drug candidate may be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize regulatory approval of our drug candidates and our ability to commence sales and generate revenues. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in the enrollment of research subjects in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of research subjects to participate in these trials. In particular, for some diseases and conditions we are or will be focused on, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and volunteers or patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the drug candidate under the clinical trial;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor volunteers or patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trial.

The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our drug candidates from applicable regulatory authorities, we will not be able to market and sell those drug candidates in those countries or regions and our business could be substantially harmed.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our drug candidates in the United States until we receive the respective approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We have not submitted a BLA or similar filing (such as marketing authorization, or MA, from the EMA for commercial sale in the European Union) or obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, PRS-080, PRS-060, our 300-series programs, our discovery stage programs, or any other drug candidates we may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

In order to market and sell our products in any jurisdiction, we or our third party collaborators must obtain separate marketing approvals in that jurisdiction and comply with its regulatory requirements. The review and approval procedures can vary drastically among jurisdictions, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals, if any, may differ substantially among jurisdictions. In addition, in many countries or regions outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country or region. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or regions. As a result, the ability to market and sell a drug candidate in more than one jurisdiction can involve significant additional time, expense and effort, and would subject us and our collaborators to the numerous and varying post-approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of our drug candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our drug candidates in foreign jurisdictions could severely limit their potential market and ability to generate revenue.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates.

We may expend our limited resources to pursue a particular drug candidate or indication that does not produce any commercially viable products and may fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our efforts on particular research programs and drug candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and drug candidates for specific indications that may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Any such failure to improperly assess potential drug candidates could result in missed opportunities and/or our focus on drug candidates with low market potential, which would harm our business and financial condition.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for our drug candidates and our business could be substantially harmed.

We depend upon independent investigators and contractors, such as CROs, universities and medical institutions, to conduct our preclinical studies and clinical trials. We rely upon, and plan to continue to rely upon, such third-party entities to execute our preclinical studies and clinical trials and to monitor and manage data produced by and relating to those studies and trials. However, we may not be able to in the future establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug candidates and materially harm our business, operations and prospects. As a result of the use of third-party contractors, we will have only limited control over certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies, including each of our clinical trials, is conducted in accordance with the applicable protocol, legal and regulatory requirements as well as scientific standards, and our reliance on any third-party entity will not relieve us of our regulatory responsibilities.

Based on our present expectations, we and our third-party contractors will be required to comply with current Good Clinical Practice, or cGCP, for all of our drug candidates in clinical development. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our contractors fail to comply with applicable cGCP, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a drug candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such drug candidate. Any agreements governing our relationships with outside contractors such as CROs, or CROs or other contractors we may engage in the future, may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If such an outside contractor terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute contractor, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable clinical trial would experience delays or may not be completed.

If our contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to a failure to adhere to our clinical protocols, legal and regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully

commercialize, the affected drug candidates. In addition, we will be unable to control whether or not they devote sufficient time and resources to our preclinical and clinical programs. These outside contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. As a result, our operations and the commercial prospects for the effected drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. These contractors may also have relationships with other commercial entities, some of whom may compete with us. If our contractors assist our competitors to our detriment, our competitive position would be harmed.

We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial and post-approval drug supplies. The development and commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements or contractual obligations and our operations could be harmed as a result.

We have no experience in drug formulation or manufacturing. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally, such as our own manufacturing facilities, to manufacture our preclinical and clinical drug supplies for use in the conduct of our preclinical studies and clinical trials or commercial quantities of any drug candidates that may obtain regulatory approval. Therefore, we lack the resources and expertise to formulate or manufacture our own drug candidates. We have entered into agreements with third-party manufacture contractors, or CMOs, for the clinical-stage manufacture of certain of our drug candidates, including PRS-080. We plan to enter into agreements with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our current and future clinical trials and/or commercial sales. We intend to establish or continue those relationships for the supply of our drug candidates, however, there can be no assurance that we will be able to retain those relationships on commercially reasonable terms, if at all. If we are unable to maintain those relationships, we could experience delays in our development efforts as we locate and qualify new CMOs. If any of our current drug candidates or any drug candidates we may develop or acquire in the future receive regulatory approval, we will rely on one or more CMOs to manufacture the commercial supply of such drugs.

Our reliance on a limited number of CMOs exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited Following BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after their receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as contractually agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, regulations and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our drug candidates by the FDA or the commercialization of our drug candidates or result in higher costs or deprive us of potential product revenues.

We expect to have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute contract manufacturer that can comply with such requirements, which we may not be able to do. Any such failure by any of our contract manufacturers would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Further, we plan to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our drug candidates for our clinical trials. We do not have, nor do we expect to enter into, any agreements for the commercial production of these raw materials, and we do not expect to have any control over the process or timing of our contract manufacturers' acquisition of raw materials needed to produce our drug candidates. Any significant delay in the supply of a drug candidate or the raw material components thereof for an ongoing clinical trial due to a manufacturer's need to replace a third-party supplier of raw materials could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates. Additionally, if our future manufacturers or we are unable to purchase these raw materials to commercially produce any of our drug candidates that gains regulatory approvals, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

Disagreements with respect to the commercial terms of our sales, licensing, purchase or manufacturing agreements may limit our commercial success.

The rights and obligations of the partners to which we may license our Anticalin® technology are governed by the licensing and collaboration agreements we enter into with those partners. In addition, our relationships with CROs and CMOs are governed by the service agreements between us and each manufacturer. Although we attempt to address the full range of possible events that may occur during the development or the manufacturing of Anticalin drug candidates and products, unanticipated or extraordinary events may occur beyond those contemplated by said agreements. Furthermore, our business relationships with our product manufacturers and our collaborators may include assumptions, understandings or agreements that are not included in our agreements with them, or that are inaccurately or incompletely represented by their terms. In addition, key terms in such agreements may be misunderstood or contested, even when both we and the other party previously believed that we had a mutual understanding of our obligations.

Any differences in interpretation or misunderstandings between us and other parties may result in substantial costs and delays with respect to the development, manufacturing or sale of Anticalin® drugs, and may negatively impact our revenues and operating results. Product manufacturers may fail to produce the products and partners may fail to develop the drug candidates under the timeline or in the manner we anticipated, and results may differ from the terms upon which we had agreed. As a result, we may be unable to supply drugs of the quality or in the quantity demanded or required. We may suffer harm to our reputation in the market from missed development goals or deadlines, and may be unable to capitalize upon market opportunities as a result. Resolution of these problems may entail costly and lengthy litigation or dispute resolution procedures. In addition, there is no guarantee that we will prevail in any such dispute or, if we do prevail, that any remedy we receive, whether legal or otherwise, will adequately redress the harm we have suffered. The delays and costs associated with such disputes may themselves harm our business and reputation and limit our ability to successfully compete in the market going forward.

Risks Related to the Commercialization of Our Drug Candidates

Even if we receive regulatory approval for any of our drug candidates, we will be subject to ongoing regulatory obligations and review. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the products may be marketed, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines or warning letters;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- product seizure or detention, or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our commercial success depends upon attaining significant market acceptance of our drug candidates, if approved, among physicians, patients, healthcare payors and other members of the medical community.

Even if we obtain regulatory approval for our drug candidates, the products may not gain market acceptance among physicians, health care payors, patients and other members of the medical community, which is critical to commercial success. Market acceptance of any drug candidate for which we receive approval depends on a number of factors, including:

- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products;
- the size of the markets for the drug candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the potential and perceived advantages of the drug candidate over alternative treatments;
- the safety of the drug candidate as demonstrated through broad commercial distribution;
- the availability of adequate reimbursement and pricing for our products from governmental health programs and other third-party payors;
- relative convenience and ease of administration;

- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of adverse effects; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

If our drug candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable, which may require us to seek additional financing.

Reimbursement may be limited or unavailable in certain market segments for our drug candidates, which could make it difficult for us to sell on a profitable basis any products for which we obtain marketing approvals.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Market acceptance and successful commercialization of any of our drug candidates that obtain regulatory approval in domestic or international markets will depend significantly on the availability of adequate coverage and reimbursement from governmental authorities, private health insurers and other third-party payors for any of our drug candidates, and may be affected by existing and future healthcare reform measures.

Pricing and reimbursement for any of our drug candidates that obtain regulatory approval is uncertain. Government authorities, private health insurers and other third-party payors decide which drugs they will cover and establish reimbursement levels for them, and obtaining coverage and reimbursement approval for a product from any such third-party payors is a time consuming and costly process. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. As a result, any denial of private or government payor coverage or inadequate reimbursement for our drug candidates, if any are commercialized, could harm our business and reduce our prospects for generating revenue.

Further, there have been, and may continue to be, legislative and regulatory proposals at the federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies. If reimbursement of our drug candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country.

We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not be able to effectively market and sell our drug candidates, if approved, or generate product revenues.

We currently have no sales, marketing or distribution capabilities and there can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any drug

candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our drug candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products.

If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our drug candidates that receive regulatory approval or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our drug candidates, which could be expensive and time consuming and which would require significant attention of our executive officers to manage. Further, may not have sufficient resources to allocate to the sales and marketing of our products.

Any failure or delay in the development of sales, marketing and distribution capabilities, either through collaboration with one or more third parties or through internal efforts, would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological advances. In addition, the competition in the anemia, asthma and cancer markets is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, fully integrated pharmaceutical or biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, and other public and private research organizations.

There are several third party drug candidates that could be competitive with drug candidates in our pipeline.

Drug candidates interfering with hepcidin function and thus competing with PRS-080 include those that are being developed by Noxxon (NOX-H94), Lilly (LY-2787106, LY-2928057), Ferrumax (FMX-8), ISIS/Xenon (XEN701), and Alnylam (ALN-HPN). Drug candidates interfering with the function of type 2 helper T cells, or Th2, the biological pathway for PRS-060, and thus competing with PRS-060, include those that are being developed by Sanofi/Regeneron (dupilimab), Roche/Genentech (lebrikizumab), Astra-Zeneca (tralokizumab, benralizumab), GSK (mepolizumab) and Teva (reslizumab). Drugs targeting immunomodulatory targets and thus competing with our 300-Series programs include those that are currently marketed by Bristol- Myers Squibb (Yervoy/ipilimumab, Opdivo/ nivolumab) and Merck (Keytruda/pembrolizumab) and drug candidates are developed by Bristol -Myers Squibb (Urelumab / anti-CD137; anti-LAG3; Anti-CD40; Lirilumab/ anti-KIR), Roche / Genentech (MPDL3280A/anti- PDL-1; RG7888 /anti-Ox40), Merck Serono (Avelumab / anti-PDL-1) and AstraZeneca (MEDI4736 / anti-PDL-1; MEDI0680 / anti-PD-1; MEDI6469/ Ox-40; tremelimumab/anti-CTLA-4). Drug candidates targeting cMet and thus competing with PRS-110 include those that are being developed by Roche / Genentech (MetMab), Eli Lilly (LY2875359) and Abbvie (ABT700). For additional

information about our third party drug candidates which could be competitive with the drug candidates in our pipeline, see "Business—Competition."

These existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenue and our business will suffer.

Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- prosecuting and enforcing intellectual property rights;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in-license novel compounds that could make our drug candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval, or discovering, developing and commercializing medicines before we do, which would have a material adverse effect on our business and ability to achieve profitability from future sales of our approved drug candidates, if any. For additional information about our competitors, please see "Business—Competition."

We could be subject to product liability lawsuits based on the use of our drug candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our drug candidates.

We could be subject to product liability lawsuits if any drug candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop on our own or with collaborators. We do not currently carry general product liability insurance. We have put in place applicable product liability insurance, covering us as sponsor and the investigators involved in our Phase Ia clinical trial of PRS-080 in healthy volunteers, in an amount of up to the lesser of €0.5 million ($0.6 million) per enrolled subject or €10 million ($12.1 million) for the Phase Ia clinical trial in its entirety. In the future, we will seek to obtain similar insurance coverage with respect to any future clinical trials of our other drug candidates, such as PRS-060 and our 300-Series programs, but we may not be able to obtain the levels of coverage desired on acceptable terms, or at all. If we do secure product liability insurance, we may subsequently determine that additional amounts of coverage would be desirable at later stages of clinical development of our drug candidates or upon commencing commercialization of any drug candidate that obtains required approvals,

but we may not be able to obtain such additional coverage amounts when needed on acceptable terms, or at all. Unless and until we obtain such insurance, we would be solely responsible for any product liability claims relating to our preclinical and clinical development activities. Further, even after any such insurance coverage is obtained, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by any insurance policies we may then have or that is in excess of the limits of our insurance coverage. We would be required to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by any product liability insurance we may obtain, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Our Intellectual Property

If we breach any of the agreements under which we license from third parties the intellectual property rights or commercialization rights to our drug candidates, particularly our license agreement with TUM, we could lose license rights that are important to our business and our operations could be materially harmed.

Under the TUM License Agreement, we in-license significant intellectual property related to our Anticalin® platforms from Technische Universität München, or TUM. Under the terms of the agreement, TUM assigns to us certain materials and records resulting from the research. We retain rights to inventions made by our employees, and TUM assigns to us all inventions made under the agreement jointly by our employees and TUM personnel, provided that our employees have made a certain inventive contribution. With respect to all other inventions made in the course of the research, TUM grants to us worldwide exclusive license rights under patents and patent applications claiming such inventions. TUM retains rights to practice these inventions for research and teaching purposes. We bear the costs of filing, prosecution and maintenance of patents assigned or licensed to us under the agreement.

As consideration for the assignments and licenses we are obliged to pay to TUM milestone payments on development of our proprietary products claimed by patents assigned or licensed to us by TUM. We also are obliged to pay low single-digit royalties, including annual minimum royalties, on sales of such products. Should we grant licenses or sublicenses to those patents to third parties, we are obliged to pay to TUM certain undisclosed variable fees as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fees are creditable against annual license payments to TUM. Our payment obligations are reduced by our proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement.

Risks Related to Managing Any Growth We May Experience

We will need to grow the size of our organization, and we may not successfully manage any growth we may achieve.

Our success will depend upon the expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational and financial resources and require us to implement and improve our operational, financial and management systems.

In addition, our ability to manage our growth effectively will hinge upon our ability to expand, train, manage and motivate our employees. As of March 23, 2016, we have 38 full-time employees and one part-time employee. As our development and commercialization plans and strategies develop, these demands may also require the hiring of additional research, development, managerial, operational, sales, marketing, financial, accounting, legal and other personnel.

Moreover, future growth could require the development of additional expertise by management and impose significant added responsibilities on members of management, including:

- effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals;

- effectively managing our internal research and development efforts such as discovery research and preclinical development;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- effectively managing our internal and external business development efforts with current or future partners, such as entering into additional collaboration arrangements and increasing out-licensing revenues;
- establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties;
- developing and managing new divisions of our internal business, including any sales and marketing segment we elect to establish;
- maintaining our compliance with public company reporting and other obligations, including establishing and maintaining effective internal control over financial reporting and disclosure controls and procedures; and
- improving our managerial, development, operational and finance systems.

We may not be able to accomplish any of those tasks, and our failure to do so could prevent us from effectively managing future growth, if any, and successfully growing our company.

Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems, could have a material adverse effect on our business, financial condition and results of operations.

We may make future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our financial condition and operating results.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue common stock or other forms of equity that would dilute our existing stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- challenges in achieving strategic objectives, cost savings and other anticipated benefits;
- increases to our expenses;
- the assumption of significant liabilities that exceed the limitations of any applicable indemnification provisions or the financial resources of any indemnifying party;
- inability to maintain relationships with key customers, vendors and other business partners of the acquired businesses;
- diversion of management's attention from their day-to-day responsibilities;

- difficulty in maintaining controls, procedures and policies during the transition and integration;
- entrance into marketplaces where we have no or limited prior experience and where competitors have stronger marketplace positions;
- potential loss of key employees, particularly those of the acquired entity; and
- that historical financial information may not be representative or indicative of our results as a combined company.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively and our business would be harmed.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to, or misappropriation by, third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from the proprietary information.

The strength of patents in the biotechnology and pharmaceutical fields can be uncertain and involve complex legal and scientific questions. No consistent policy regarding the breadth of claims allowed in patents has emerged to date in the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced, or that the scope of any patent rights could provide a sufficient degree of protection that could permit us to gain or keep our competitive advantage with respect to these products and technologies. For example, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings (e.g. at the United States Patent and Trademark Office, or the USPTO, or the European Patent Office, or the EPO) in connection with patent rights, which may be costly whether we win or lose.

As a result, the patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any drug candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered drug candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our drug candidates.

While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for our drug candidates, the applicable patents may not meet the specified conditions for eligibility for any such term extension and, even if eligible, we may not be able to obtain any such term extension. Further, because filing, prosecuting, defending

and enforcing patents in multiple jurisdictions can be expensive, we may elect to pursue patent protection relating to our drug candidates in only certain jurisdictions. As a result, competitors would be permitted to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, any of which could compete with our drug candidates.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know-how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secrets and other intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.

Our research, development and commercialization activities, as well as any drug candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims that cover the use or manufacture of our drug candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our drug candidates infringes upon one or more claims of these patents. If our activities or drug candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such drug candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable.

Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and/or redesign our infringing drug candidates or alter related formulations, processes, methods or other technologies, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us because they have substantially greater resources. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our drug candidates and our business could materially suffer.

We may desire to, or be forced to, seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.

Third parties may also hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify drug candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those drug candidates. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

The patent protection covering some of our drug candidates may be dependent on third parties, who may not effectively maintain that protection.

While we expect that we will seek to gain the right to fully prosecute any patents covering drug candidates we may in-license from third-party owners, it is possible that the platform technology patents that cover our drug candidates remain controlled by our licensors. Similarly, some of our future licensing partners may retain the right, or may seek the rights, to prosecute patents covering the drug candidates we license to them and we may grant such rights to those partners for business reasons. If such third parties fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected drug candidates may suffer.

Certain technologies and patents have been developed with partners and we may face restrictions on this jointly-developed intellectual property.

We have entered into agreements with a number of commercial partners, including university partners, which cover intellectual property. We have, in some cases individually and in other cases along with our partners, filed for patent protection for a number of technologies developed under these agreements and may in the future file for further intellectual property protection and/or seek to commercialize such technologies. Under some of these agreements, certain intellectual property developed by us and the relevant partner may be subject to joint ownership by us and the partner and our commercial use of such intellectual property may be restricted, or may require written consent from, or a separate agreement with, the partner. In other cases, we may not have any rights to use intellectual property solely developed and owned by the partner. If we cannot obtain commercial use rights for such jointly-owned intellectual property or partner-owned intellectual property, our future product development and commercialization plans may be adversely affected.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming and distract management.

If we pursue any litigation, a court may decide that a patent of ours or any of our licensors' is not valid or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of, or the amount of damages that could be awarded resulting from, any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put

one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in those jurisdictions.

Interference proceedings provoked by third parties or brought by the USPTO or at its foreign counterparts (such as the EPO) to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all.

Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed.

We are seeking patent protection for certain of our technology and drug candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and drug candidates, our business may be adversely impacted.

In addition, issued patents and pending applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents unenforceable or by prematurely terminating pending applications.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our Anticalin®-brand technology and some of our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors, investigators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If we fail to protect our trademark rights, competitors may be able to take advantage of our goodwill, which would weaken our competitive position, reduce our revenues and increase our costs.

We believe that the protection of our trademark rights is an important factor in product recognition, maintaining goodwill, and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register, maintain and enforce our trademark rights. If we do not adequately protect our rights in our trademarks from infringement, any goodwill that we have developed in those trademarks could be lost or impaired.

Third parties may claim that the sale or promotion of our products, when and if we have any, may infringe on the trademark rights of others. Trademark infringement problems occur frequently in connection with the sale and

marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks we use are found to infringe upon the trademark of another company, we could be liable for damages and be forced to stop using those trademarks, and as result, we could lose all the goodwill that has been developed in those trademarks.

Certain of our employees and their inventions are subject to German law.

Many of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and such employees or ex-employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees retained rights to patents they invented or co-invented prior to 2009. Although most of these employees have subsequently assigned their interest in these patents to us, there is a risk that the compensation we provided to them may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

The future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use.

As part of our business strategy, we intend to license our Anticalin® technology and sell our potential products, if any, in many different countries. As a result, we may do business with third parties in countries where intellectual property rights have been or are routinely disregarded, and the future growth of our business may expose our intellectual property to a high risk of counterfeiting or unauthorized use. Although we attempt to obtain broad international intellectual property rights for our Anticalin technology and proteins, we cannot guarantee that such rights, to the extent we can obtain them, will be enforceable in a timely fashion or at all in any particular country or jurisdiction, or that if enforced, will offer us adequate commercial protection or adequate redress for any harm suffered. Counterfeiting or unauthorized use of our technologies or products may also expose our business to harm for which no adequate monetary redress exists, and to the extent we are unable to stop such use, may cause us to lose rights with respect to intellectual property that is crucial to our business. Any such misuse of our intellectual property may have a substantial negative impact on our business and revenues, and may cause our business to fail.

Risks Related to our Employees

If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified personnel. We are highly dependent on our management, scientific and medical personnel, especially Stephen S. Yoder, our Chief Executive Officer and President, whose services are critical to the successful implementation of our drug candidate development, our business development and partnerships, and our regulatory and commercialization strategies. Further, as our approach is built in part upon the drug discovery and development experience of our drug development team, which we believe is a significant contributor to our competitive advantage, we are dependent on the maintenance and growth of that team with qualified members containing high levels of expertise in specific scientific fields. We currently have 39employees, and we may in the future hire additional employees for research and development or general and administrative activities.

We are not aware of any present intention of any of our executive officers or other members of our senior management team to leave our company, but our industry tends to experience a high rate of turnover of management personnel and our employees are generally able to terminate their relationships with us on short notice. Pursuant to German employment law, our employment arrangements with employees of Pieris GmbH are governed by employment contracts which provide certain defined terms for either party to terminate the employment relationship.

The loss of the services of any of our executive officers, in particular Mr. Yoder, or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior and mid-level managers as well as junior and mid-level scientific and medical personnel.

Moreover, there is intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other related businesses. Many of the other companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles, longer histories in the industry and greater ability to provide valuable cash or stock incentives to potential recruits than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we are able to offer as an early stage company. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize drug candidates will be limited.

We may be subject to labor claims brought by our employees against us.

In the United States, an employment relationship with no specified duration is presumed to be employment "at-will" and the employer or employee may terminate the employment relationship at any time, with or without cause, except for public policy reasons including discrimination, participating in union activity or refusing to carry out an activity that violates the law.

In contrast, in Germany, there is no analogous doctrine of "employment at will". By law, German employees must have written employment contracts that reflect the key aspects of the employment relationship. Our relations between German employers and employees are extensively regulated under German labor and employment laws and regulations. German employees enjoy, in particular, special protection against dismissals provided the employee has been employed by a company for more than six months and such company employs more than 10 employees.

German employment termination law is regulated by various codes, in particular the *Kündigungsschutzgesetz* (German Termination Protection Act) and is intended to give the employee maximum protection against unfair dismissal, including among other things:

- the employer must observe the applicable notice period, which is ordinarily determined by law (between four weeks and seven months, depending upon the length of employment), if a longer period is not otherwise agreed by the parties, and has to deliver a written notice of termination to the employee;
- for companies with more than ten employees, the German Termination Protection Act generally restricts termination of employment if the employee has been employed for more than six months, wherein the employee may be terminated only for a particular reason, including certain behavioral or personal reasons relating to the employee or certain developments relating to the business of the employer, such as a business restructuring which reduces the number of employee positions;
- special termination protection against unlawful dismissal applies to several other groups of employees, such as an employee that is an officially acknowledged handicapped person, an employee who was appointed as a company's data protection officer or as a member of the works council of a company, if

any, an employee on three years' maternity leave or a pregnant employee; in these cases, approval of various German authorities is required prior to termination but usually very difficult to obtain; and

- if a company engages in a mass layoff, which is deemed to occur when the employer intends to dismiss a large percentage of its employees during a one-month period, prior written notification to the German employment office is required.

In this regard, if we downsize Pieris for any reason and fail to adhere to the complex requirements articulated by the employee protection law, we could face legal actions brought by affected employees or former employees, and, as a result, we may incur operational or financial losses and the attention of our executive officers may be distracted from managing our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employers. Litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, provide accurate information to the FDA or EMA, comply with manufacturing standards we have established, comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions and procedures we currently take or may establish in the future as our operations and employee base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by our employees to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to the Ownership of our Common Stock

Our share price is expected to be volatile and may be influenced by numerous factors, some of which are beyond our control.

Market prices for shares of biotechnology companies such as ours are often volatile, and the quoted price of our common stock is therefore likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the drug candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those drug candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our drug candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our drug candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our drug candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our drug candidates;
- our dependence on third parties, including CROs as well as our current and potential partners that produce companion diagnostic products;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition, other biotechnology companies or our competitors' programs could have positive or negative results that impact their stock prices and their results or stock fluctuations could have a positive or negative impact on our stock price regardless of whether such impact is direct or not. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 of the Exchange Act establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (i) that a broker or dealer approve a person's account for transactions in penny stocks in accordance with the provisions of Rule 15g-9; and (ii) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased, provided that any such purchase shall not be effected less than two business days after the broker or dealer sends such written agreement to the investor.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (i) obtain financial information, investment experience and investment objectives of the person and (ii) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be reasonably expected to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which: (i) sets forth the basis on which the broker or dealer made the suitability determination; and (ii) in highlight form, confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result, it may be more difficult to execute trades of our common stock which may have an adverse effect on the liquidity of our common stock and your investment.

If securities or industry analysts do not publish, or cease publishing, research or publish inaccurate or unfavorable research about our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business, markets or competitors. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or

publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. However, as discussed in detail below, as an emerging growth company, we are not required to obtain an auditor attestation. As a private company, we were not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the Acquisition. Our management team and Board of Directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, issuers that qualify as "emerging growth companies" under the JOBS Act will not be required to provide an auditor's attestation report on internal controls for so long as the issuer qualifies as an emerging growth company. We currently qualify as an emerging growth company under the JOBS Act, and we may choose not to provide an auditor's attestation report on internal controls. However, if we cannot favorably assess the effectiveness of our internal control over financial reporting, or if we require an attestation report from our independent registered public accounting firm in the future and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We have had material weaknesses in our internal control over financial reporting in the past. Although such weaknesses have been remediated, we cannot assure you that we will be successful in remediating any material weaknesses in our internal control over financial reporting in the future. Any failure to implement and document new and more precise monitoring controls or to implement organizational changes including skillset enhancements through resource changes or education to improve detection and communication of financial misstatements across all levels of the organization could result in additional material weaknesses, result in material misstatements in our financial statements and cause us to fail to meet our reporting obligations, which in turn could cause the trading price of our common stock to decline.

Shares of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company."

Prior to the closing of the Acquisition, we were deemed a "shell company" under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Form 8-K reports. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future. The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline.

If we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 300,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the terms, limitations, voting rights, relative rights and preferences and variations of each series that our Board of Directors may determine from time to time. Upon the closings of the private placement of our common stock on December 17, 18 and 23, 2014, we issued an aggregate of 6,779,510 shares of our common stock, with the private placement, we issued 542,360 shares of common stock issuable upon exercise of common stock purchase warrants issued to the placement agents thereof and their designees, and in connection with public offering in July 2015 we issued an aggregate of 10,302,736 shares of our common stock. During the year 2015 we issued an aggregate of 245,765 shares of our common stock to consultants in exchange for their services under several contracts. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuances of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may have rights, preferences and privileges that are superior to those of our common stock, and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2015, a total of 39,833,023 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The resale of shares covered by our effective resale registration statement could adversely affect the market price of our common stock in the public market, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. We filed a registration statement with the SEC, which was declared effective on May 11, 2015, to register the resale of 27,321,870 shares of our common stock, which represents all of the shares of our common stock issued and sold in our private placement consummated in December 2014, shares of our common stock issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition on December 17, 2014, and shares of common stock issuable upon exercise of common stock purchase warrants issued in connection with the closings of the private placement in December 2014. Such shares represented approximately 69% of our outstanding shares of common stock as of March 23, 2016. The resale registration statement permits the resale of these shares at any time without restriction. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statement, we may continue to offer shares covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Even after giving effect to the funds raised in the past, we expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Pursuant to our 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 3,200,000 shares of our common stock and, as of December 31 2015, we have granted options to purchase 2,707,329 shares of our common stock. The Pieris Plan also includes an “evergreen” provision which provides that the number of shares of our common stock reserved for issuance under the Pieris Plan shall be automatically increased on January 1 of each of year by the lesser of (i) 1,000,000 shares, (ii) 4% of the number shares of our common stock outstanding on such date, and (iii) such other amount determined by the Board of Directors. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Anti-takeover provisions in our organizational documents could delay or prevent a change of control.

Certain provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws may have an anti-takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its interests, including attempts that might result in a premium over the market price for the shares held by our stockholders.

These provisions provide, among other things:

- a classified Board of Directors with staggered three-year terms;
- the ability of our Board of Directors to issue one or more series of preferred stock with voting or other rights or preferences that could have the effect of impeding the success of an attempt to acquire us or otherwise effect a change of control;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at stockholder meetings;
- certain limitations on convening special stockholder meetings and the prohibition of stockholder action by written consent; and
- directors may only be removed for cause and only by the affirmative vote of the holders of at least eighty percent (80%) of the voting power of all of the then-outstanding shares of our capital stock entitled to vote at an election of directors, voting together as a single class.

These anti-takeover provisions, including those noted above, could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. See "Description of Capital Stock".

Our Amended and Restated Articles of Incorporation designates the Eighth Judicial District Court of Clark County, Nevada, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and therefore limit our stockholders' ability to choose a forum for disputes with us or our directors, officers, employees or agents.

Our Amended and Restated Articles of Incorporation provide that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for any (i) derivative action or proceeding brought in the name or right of the corporation or on its behalf, (ii) action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to the corporation or any of our stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Chapters 78 or 92A of the Nevada Revised Statutes or any provision of our articles of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our Amended and Restated Articles of Incorporation further provide that any person purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed, to the fullest extent permitted by law, to have notice of and consented to the foregoing provision.

We believe the choice-of-forum provision in our Amended and Restated Articles of Incorporation will help provide for the orderly, efficient and cost-effective resolution of Nevada-law issues affecting us by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents. While there is no Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware ruled in June 2013 that choice-of-forum provisions of a type similar to those included in our Amended and Restated Articles of Incorporation are not facially invalid under corporate law and constitute valid and enforceable contractual forum selection clauses. However, if a court were to find the choice-of-forum provision in our Amended and Restated Articles of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

The elimination of personal liability of our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Amended and Restated Articles of Incorporation eliminate to the furthest extent permitted under Nevada law the personal liability of our directors and officers to us, our stockholders and creditors for damages as a result of any act or failure to act in his or her capacity as a director or officer. Further, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and individual indemnification agreements that we have entered with each of our directors and officers provide that we are obligated to indemnify, subject to certain exceptions, each of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, to advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for such damages, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. We currently intend to retain all future earnings to fund the development and growth of our business. Any future payment of cash dividends in the future will be at the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the Board of Directors deems relevant. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

We will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

As a public company listed on the NASDAQ Capital Market, and particularly if and after we cease to be an “emerging growth company” or a “smaller reporting company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company and that we did not incur prior to the listing of our common stock on the NASDAQ Capital Market, including costs associated with public company reporting requirements. In addition, the rules and regulations of the SEC and the NASDAQ Capital Market impose numerous requirements on public companies, including requirements relating to our corporate governance practices and requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, with which we will now need to comply. Further, since we are subject to the Exchange Act, we are required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We are unable currently to estimate these costs with any degree of certainty.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company under the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public

Company Accounting Oversight Board. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to take advantage of this extended transition period. Since we will not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our financial statements may not be comparable to the financial statements of companies that comply with the effective dates of those accounting standards.

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (3) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (4) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” may make it harder for investors to analyze our results of operations and financial prospects.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a “smaller reporting company”, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $75 million and annual revenues of less than $50 million during the most recently completed fiscal year. In the event that we are still considered a “smaller reporting company,” at such time we cease being an “emerging growth company”, we will be required to provide additional disclosure in our SEC filings. However, similar to “emerging growth companies”, “smaller reporting companies” are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in a registration statement under the Exchange Act on Form 10. Decreased disclosures in our SEC filings due to our status as a “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

We lease 1,414 square meters of office and laboratory space in Freising, Germany. This lease may be terminated by either party subject to an 8-month notice period, provided, however, that such period must finish at the end of a quarter and, if not, the notice period will be extended to the following quarter-end. We lease 3,950 square feet of office space in Boston, MA under a sublease that houses our executive offices and certain administrative functions. This sublease shall expire on February 27, 2022 or such earlier date pursuant to the termination provisions of the Sublease Agreement. We believe that our facilities are sufficient to meet our needs and will look for suitable additional space as and when needed.

Item 3. LEGAL PROCEEDINGS

Arbitration Proceeding with Technische Universität München

On March 20, 2014, Pieris instituted arbitration proceedings, or the TUM Arbitration, against Technische Universität München, or Munich Technical University and hereafter TUM, to address issues regarding the calculation of payments due from Pieris to TUM under Pieris's Research and Licensing Agreement with TUM, as amended, or the TUM License Agreement. Pursuant to the terms of the TUM License Agreement, the arbitration is proceeding in Munich, Germany and governed by German law, in accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit, or DIS.

On July 4, 2003, or the Effective Date, Pieris and TUM entered into the TUM License Agreement, as superseded and replaced on July 26, 2007, under which TUM has exclusively licensed, or in some cases assigned, to Pieris certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, Pieris agreed to pay to TUM certain undisclosed annual license fees, milestones and royalties for its own proprietary drug development and sales, as well as an undisclosed variable fee as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fees are creditable against annual license payments to TUM.

As required by the TUM License Agreement, Pieris provided to TUM its calculation of the Out-License Fee owed by Pieris to TUM for the period beginning on the Effective Date and ending on December 31, 2012, the Dispute Period, in the amount of $0.4 million excluding value-added tax. TUM has asserted that, under the TUM License Agreement, the Out-License Fee due to TUM for the Dispute Period amounts to $3.4 million excluding value-added tax in the aggregate and has threatened to terminate the TUM License Agreement if the Out-License Fee is not paid. We believe that if TUM sought to terminate the license agreement for cause as a result of this dispute, it would potentially face wrongful termination claims for substantial damages if the arbitral tribunal in the TUM Arbitration sides with Pieris in its final decision regarding the proper amount of the Out-License Fee. We commenced the TUM Arbitration to request that the arbitration tribunal hold that our calculation of the payments owed to TUM is accurate and shall govern all current and future payments due in respect of the Out-License Fee under the TUM License Agreement.

On November 19, 2015, we received notification from the DIS of the arbitration tribunal's award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company's request for declaratory judgment and granted TUM's counterclaim in an amount of only €0.9 million ($0.9 million), of which, $0.6 million is recorded as research and development expense in the consolidated statement of operations for the 2015 period due to a previous liability of $0.3 million recorded for the arbitration settlement as of December 31, 2014. Interest expense of $0.2 million was also included in the settlement and is recorded in the consolidated statement of operations as interest expense, net. The tribunal dismissed the remainder of TUM's counterclaim.

The Tribunal also ruled that TUM must reimburse us in the amount of €0.1 million ($0.1 million) for legal fees incurred and dismissed TUM's claim for reimbursement of its costs. We have decided not to challenge the award and paid the amount as calculated by the arbitration tribunal. The deadline for filing a motion to set aside the award expired on February 15, 2016.

As of the date of this Annual Report on Form 10-K, we are not currently involved in any material legal proceedings. However, from time to time, we could be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the Nasdaq Capital Market under the symbol "PIRS." On June 30, 2015 our common stock began trading on the Nasdaq Capital Market. Our common stock was first publicly traded on the OTC Markets, OTCPink tier of the OTC Markets Group, Inc commencing on January 28, 2015. The following table sets forth, for the periods indicated, the high and low closing bid quotations for our common stock, as reported by NASDAQ, since the common stock commenced public trading:

	Common Stock	
	High	Low
Year Ended December 31, 2015:		
First Quarter	$3.25	$2.75
Second Quarter	$4.40	$2.00
Third Quarter	$3.70	$1.74
Fourth Quarter	$3.08	$1.54
Year Ended December 31, 2014:		
First Quarter	(1)	(1)
Second Quarter	(1)	(1)
Third Quarter	(1)	(1)
Fourth Quarter	$2.60	$0.25

(1) There was no market for our common stock during this period.

Stockholders

As of March 20, 2016, there were 148 stockholders of record of our common stock.

Dividends

We have never declared nor paid any cash dividends to stockholders. We do not intend to pay cash dividends on our common stock for the foreseeable future, and currently intend to retain any future earnings to fund our operations and the development and growth of our business. The declaration of any future cash dividend, if any, would be at the discretion of our Board of Directors (subject to limitations imposed under applicable Nevada law) and would depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions.

Unregistered Sales of Securities

On August 17, 2015, the Company issued an option grant to Louis A. Matis, M.D., its Chief Development Officer, as a new hire inducement grant pursuant to NASDAQ Listing Rule 5635(c)(4) and Section 4(a)(2) of the Securities Act. Dr. Matis's option grant is for the purchase of an aggregate of 500,000 shares of Common Stock at a price per share of $3.36 subject to his continued employment with the Company.

On November 20, 2015, we entered into a letter agreement, pursuant to which we issued 68,493 shares of our common stock to an advisor, in exchange for certain consulting and other services. The shares issued in connection with consulting agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

Not applicable.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described under the heading "Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K. You should review the disclosure under the heading "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company that discovers and develops Anticalin® based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immune-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies, which are naturally occurring low-molecular weight human proteins typically found in blood plasma and other bodily fluids.

Each of our development programs focus on the following:

- *300-Series oncology drug candidates* are multispecific Anticalin®-based proteins designed to engage immunomodulatory targets and consist of a variety of multifunctional biotherapeutics that genetically link an antibody with one or more Anticalin proteins, thereby constituting a multispecific protein;
- *PRS-060* is a drug candidate that binds to the IL-4RA receptor, thereby inhibiting IL-4 and IL-13, two cytokines, small proteins mediating signalling between cells within the human body, known to be key mediators in the inflammatory cascade that causes asthma and other inflammatory diseases; and
- *PRS-080* is an Anticalin protein that binds to hepcidin, a natural regulator of iron in the blood. It has been designed to target hepcidin for the treatment of functional iron deficiency in anemic patients with chronic kidney disease particularly in end-stage renal disease patients requiring dialysis.

Each of our programs are in varying stages of clinical or pre-clinical efforts:

- 300-Series lead candidates—We are conducting preclinical experiments on a number of 300-Series lead candidates including PRS-343. The compounds within these experiments aim to activate the immune system in the tumor microenvironment, with the goal of increasing efficacy and improving safety. In December 2015, we signed our first partnership under the immuno-oncology program with Roche;
- PRS-080—In June 2015, we completed dosing of healthy volunteers in a Phase Ia clinical trial. In the trial, no dose-limiting toxicities were observed and a maximum tolerated dose was not reached. Detailed data was published on this study during the fourth quarter of 2015 and our safety profile was validated; and
- PRS-060—Currently in preclinical development, and we intend to begin a Phase I clinical trial with this program in 2017.

Our core Anticalin® technology and platform was developed in Germany, and we have partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India. These include existing agreements with Daiichi

Sankyo Company Limited ("Daiichi Sankyo"), Sanofi Group (formerly Sanofi-Aventis and Sanofi-Pasteur SA, "Sanofi"), and F.Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. ("Roche") pursuant to which our Anticalin platform has consistently achieved its development milestones. We have discovery and preclinical collaboration and service agreements with both academic institutions and private firms. We have also begun to establish a greater U.S. presence and take advantage of the U.S. capital markets, additional potential corporate partners, and the broad expertise found in the biotechnology industry in the United States.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. For the years ended December 31, 2015 and 2014, we reported net loss of $14.1 million and net income of $9.8 million, respectively. As of December 31, 2015, we had an accumulated deficit of $79.9 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the fiscal years ended December 31, 2015 and 2014 were primarily from license and collaboration agreements with our partners, and, to a lesser extent, from grants from government agencies.

A significant portion of our operations are conducted in countries other than the United States. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rates between the euro and the U.S. dollar. All assets and liabilities denominated in euros are translated into U.S. dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the average rate during the period. Equity transactions are translated using historical exchange rates. Adjustments resulting from translating foreign currency financial statements into U.S. dollars are included in accumulated other comprehensive loss. We may incur negative foreign currency translation changes as a result of changes in currency exchange rates.

Acquisition

On December 17, 2014, Pieris, Pieris GmbH and the former stockholders of Pieris GmbH entered into an Acquisition Agreement ("Acquisition Agreement"), and completed the Acquisition, pursuant to which the stockholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH in exchange for shares of Pieris common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of Pieris, which we refer to as the Acquisition.

On December 5, 2014, Pieris completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock split became 13,863,647 shares of common stock outstanding immediately thereafter. On December 16, 2014, prior to the closing of the Acquisition, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc.," and increase its authorized capital stock from 75,000,000 shares of common stock, par value $0.001 per share, to 300,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share. On December 17, 2014, Pieris transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock. All share and per share numbers in this Annual Report on Form 10-K relating to our shares of common stock have been adjusted to give effect to the stock split described above, unless otherwise stated.

At the closing of the Acquisition, Pieris issued an aggregate of 20,000,000 shares of its common stock to the former stockholders of Pieris GmbH in exchange for all of the outstanding shares (common and preferred) of Pieris GmbH's capital stock.

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, section 805 entitled, "*Business Combinations*," Pieris GmbH was considered the accounting acquirer in the Acquisition and accounted for the transaction as a capital transaction. Consequently, the assets and liabilities and the historical operations that will be reflected in our financial statements are those of Pieris GmbH and are be recorded at the historical cost basis of Pieris GmbH.

TUM Arbitration

Since March 20, 2014, the Company was in arbitration proceedings, or the TUM Arbitration, against Technische Universität München, or Munich Technical University and hereafter TUM, to address issues regarding the calculation of payments due from the Company to TUM under the TUM License Agreement. Under the agreement, TUM has exclusively licensed, or in some cases assigned, to Pieris GmbH certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, Pieris GmbH agreed to pay to TUM certain annual license fees, milestones and royalties for its own proprietary drug development and sales, as well as a variable fee as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fee is creditable against annual license payments to TUM. As required by the agreement, Pieris GmbH provided to TUM its calculation of the Out-License Fee for the period beginning July 4, 2003 and ending on December 31, 2012 in the amount of $0.4 million excluding value-added tax. TUM has asserted that the Out-License Fee for this period amounts to €2.5 million ($3.0 million) excluding value-added tax and has threatened to terminate the license agreement if the Out-License Fee is not paid. We instituted arbitration to request confirmation that our calculation of the payments owed to TUM is accurate and will govern all current and future payments due in respect of the Out-License Fee under the agreement.

On November 19, 2015, the Company received notification from the arbitration tribunal of its award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company's request for declaratory judgment and granted TUM's counterclaim in an amount of €0.9 million ($0.9 million), plus interest expense of $0.2 million. The tribunal dismissed the remainder of TUM´s counterclaim. The Tribunal also ruled that TUM must reimburse us in the amount of €0.1 million ($0.1 million) for legal fees incurred and dismissed TUM's claim for reimbursement of its costs.

Key Financial Terms and Metrics

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

Revenues

We have not generated any revenues from product sales to date, and we do not expect to generate revenues from product sales for the foreseeable future. Our revenues for the last two years have been primarily from the license and collaboration agreements with Sanofi Group, or Sanofi, and Daiichi Sankyo Company Limited, or Daiichi Sankyo and, to a much lesser extent, grants from government agencies.

The revenues from Sanofi and Daiichi Sankyo have been comprised primarily of upfront payments, research and development services and milestone payments. We recognized revenues from upfront payments under these agreements on a straight-line basis over the required service period because we determined that the licenses to which the payments related did not have standalone value. Research service revenue is recognized when the costs are incurred and the services have been performed. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the probability of the achievement of the milestone is near certain, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment.

We expect our revenues for the next several years to consist of upfront payments, research funding and milestone payments from strategic collaborations we currently have or may establish in the future.

Research and Development Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our clinical and preclinical drug candidates and programs. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. Our current development plans focus on three lead drug candidates: PRS-080, PRS-060 and 300-series. These programs consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs that are directly attributable to the creation of certain of our Anticalin ® drug candidates and are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and
- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

In 2016 we expect our research and development expenses to increase significantly as a result of continuing to further our drug candidates and programs.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting and legal services.

Results of Operations

Comparison of Years Ended December 31, 2015 and December 31, 2014

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Revenues	$ 2,932	$ 5,365
Research and development expenses	(8,245)	(5,600)
General and administrative expenses	(8,368)	(6,963)
Other expense, net	(174)	(2,652)
Income tax provision	(204)	—
Net loss	$ (14,059)	$ (9,850)

Revenues

The following table provides a comparison of revenues for the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Upfront payments	$ —	$ 473
Research and development services	5	877
Milestone payments	2,539	3,185
Grants and other revenues	388	830
Total	$ 2,932	$ 5,365

We did not record any revenues from upfront payments during the year ended December 31, 2015. The revenues from upfront payments recorded during the year ended December 31, 2014 were associated with payments from our collaboration partners. Revenues from research and development services decreased $0.9 million, from 2014 to 2015 due to the successful hand over of all collaboration projects in 2014. During the year ended December 31, 2014 we received research funding from collaboration partners for two collaboration projects.

Pieris recorded collaboration milestone payments of $2.5 million for the year ended December 31, 2015 compared to $3.2 million for the year ended December 31, 2014. The decrease relates to two development milestones achieved during the year ended December 31, 2015 compared to four development milestones achieved during the year ended December 31, 2014.

Pieris recorded $0.4 million in grant and other revenues for the year ended December 31, 2015 compared to $0.8 million in grant and other revenues during the year ended December 31, 2014. This decrease results from a higher reimbursement from the European Commission for PRS-080´s development during the last quarter of 2014.

Research and Development Expenses

The following table provides a comparison of the research and development expenses for our drug candidates and projects for the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
PRS-060	$ 532	$ 86
PRS-080	1,631	1,384
PRS-300 series	2,917	596
Other R&D activities	3,165	3,534
Total	$ 8,245	$ 5,600

Total research and development expenses were $8.2 million for the fiscal year ended December 31, 2015 as compared to $5.6 million for the fiscal year ended December 31, 2014.

The $2.6 million increase in total research and development expenses in the fiscal year ended December 31, 2015 compared to the fiscal year ended December 31, 2014 is primarily due to a $2.3 million increase for consulting expenses, labs supplies and personnel costs associated with our 300-Series programs in the fiscal year ended December 31, 2015. Our PRS-060 program increased $0.4 million due to increased preclinical efforts involving research studies. Our PRS-080 program increased by $0.2 million due to the Phase Ia clinical trial activity that began in late 2014, and was completed during 2015, as well as clinical manufacturing costs. Other R&D

activities decreased by $0.3 million. Included in other R&D activities in the 2015 period is $0.9 million of license fees associated with the TUM license agreement offset by an estimated tax credit of $0.3 million attributable to 2015 R&D expenses incurred in Australia and an additional reduction of costs related to other projects, as we focused work on our major projects during 2015.

General and Administrative Expenses

General and administrative expenses were $8.4 million for the fiscal year ended December 31, 2015 as compared to $7.0 million for the fiscal year ended December 31, 2014. The increase of $1.4 million resulted primarily from a $1.1 million increase in investor relations expense, directors and officer insurance premiums, and board fees associated with being a public company. Personnel and travel related costs increased by $0.6 million, offset by a decrease of $0.6 million in lower consulting costs. Stock compensation expenses increased by $0.2 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. For the 2015 period an additional amount of $0.1 million is included for the estimated Massachusetts Net Worth Tax.

Interest Expense & Other Income (Expense), net

Other expense decreased to $0.2 million in the fiscal year ended December 31, 2015 from $2.7 million for the fiscal year ended December 31, 2014. This $2.5 million decrease results primarily from the conversion of the convertible bridge loan in late 2014 that we obtained in November 2012, into shares of common stock and relates to the beneficial conversion feature thereto in an amount of $2.2 million and $0.3 million in lower interest and other costs. The beneficial conversion feature was a nondetachable conversion feature which was in the money at the conversion date, since its effective exercise price was less than the current fair value of the share.

Other expenses, net in the 2015 period relate to the interest charge associated with the TUM arbitration settlement reached in the fourth quarter of 2015.

Liquidity and Capital Resources

Through December 31, 2015, we have funded our operations with $169.7 million of cash that has been obtained from the following main sources: $102.7 million from sales of equity; $6.5 million from loans; $14.2 million from grants from government agencies; and $46.4 million in total payments received under license and collaboration agreements, including $7.9 million for research and development services costs from Daiichi Sankyo and Sanofi. We expect that reimbursements of our development costs by Daiichi Sankyo and Sanofi will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future.

As of December 31, 2015, we had a total of $29.3 million in cash and cash equivalents. Our cash and cash equivalents are highly liquid investments with original maturities of 90 days or less at date of purchase, and consist of cash in operating accounts.

We have experienced operating losses since its inception and had a total accumulated deficit of $79.9 million as of December 31, 2015. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception including the year ended December 31, 2015. These losses have resulted in significant cash used in operations. During the fiscal years ended December 31, 2015 and 2014, our cash used in operations was $12.7 million and $5.1 million, respectively. We have several research and development programs underway in varying stages of development and we expect they will be continue to consume increasing amounts of cash for development, conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of our 300-Series, including PRS-343. PRS-080 and PRS-060 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years. We also expect to incur increased costs in connection with operating and growth as a public company.

In April 2014, we entered into a repayment agreement with tbg Technologie-Beteiligungs-Gesellschaft mbH ("TBG), the subsidiary of KfW Bank, Frankfurt ("KfW), regarding our repayment of our liabilities to TBG outstanding at December 31, 2013 in a total amount €1.2 million ($1.3 million). These liabilities were repaid during 2015 and as of December 31, 2015 there were no liabilities to TBG owed.

On December 17, 2014 we entered into a Securities Purchase Agreement, with the investors, providing for the issuance and sale to such investors of an aggregate of 6,779,510 shares of our common stock in the Private Placement for gross proceeds to us of $13.6 million. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.0 million.

On July 6, 2015 the Company closed a public offering of an aggregate of 9,090,909 shares of the Company´s common stock at a purchase price of $2.75 per share. On July 28, 2015 the underwriters exercised their option to purchase an additional 1,211,827 shares of common stock at the public offering price of $2.75 per share. Gross proceeds from the offering, including the over-allotment option, were $28.3 million and net proceeds were approximately $25.8 million.

We will need to obtain additional funding in order to continue our operations and pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. Our requirements for additional capital will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates and any products that we may develop;
- the number and characteristics of drug candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We cannot be sure that future funding will be available to us on acceptable terms, or adequate enough at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress for our 300-series programs, including PRS-343 and PRS-080 and PRS-060 could have a material adverse impact on our ability to raise additional capital.

We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our drug candidates, future revenue streams, research programs or product

candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Contractual Obligations

Leases

We lease office and laboratory space in Freising, Germany. The lease has a defined termination date which is the end of a notification period of eight months at the end of each quarter. On August 27, 2015 we entered into an Agreement of Sublease (the "Sublease Agreement") with Berenberg Capital Markets LLC (the "Sublandlord"). Under the Sublease Agreement, the Sublandlord will sublease to us approximately 3,950 square feet in Boston, MA. The term of the lease shall expire on February 27, 2022. The Sublease Agreement provides for free rent for the first two months in addition to scheduled rent increases that are not dependent on future events.

Our policy is to record rent expense on a straight-line basis over the lease term period. As of December 31, 2015, we recognized rent expense in an amount of $18,399 under the Sublease Agreement. Rent expense under our operating lease for our Freising, Germany based facility was $0.4 million and $0.3 million for the years ended December 31, 2015 and 2014, respectively.

Our contractual commitments of the non-cancellable portion under theses operating leases as of December 31, 2015 are as follows:

	Total
2016	$ 318,186
2017	188,009
2018	191,959
2019	195,909
2020	199,859
Thereafter	238,371
Total minimum lease payments	$1,332,293

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Management makes estimates and exercises judgment in revenue recognition, share-based payments and income taxes. Judgments must also be made about the disclosure of contingent liabilities, and these estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates and under different assumptions or conditions.

We have identified the following accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results could differ from these estimates and such differences could be material.

Revenue Recognition

Multiple-element arrangements

When evaluating multiple-element arrangements, we identify the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based whether the delivered element has stand-alone value to the collaborator or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. We used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because we do not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, we consider market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating our best estimate of selling price, we evaluate whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

We typically receive upfront, nonrefundable payments when licensing our intellectual property in conjunction with a research and development agreement. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research capabilities of the partner and the availability of Anticalin® technology research expertise in the general marketplace.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, we generally recognize revenue attributable to the license on a straight-line basis over our contractual or estimated performance period, which is typically the term of our research and development obligations. When management believes the license to its intellectual property has stand-alone value, we recognize revenue attributed to the license upon delivery. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue we record in future periods.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, we are at risk as to whether the collaborative partner will choose to exercise the options to secure additional licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional licenses are considered substantive, we determine whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and

incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and we apply the multiple-element revenue recognition criteria to determine accounting treatment. All of our agreements with options have been determined to include substantive options.

Revenue resulting from our research and development services efforts in multiple-element arrangements in which our research and development service efforts are considered deliverable are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

Milestone payments

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

We aggregate milestones into four categories (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin® protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceed net sales as defined in each agreement.

For revenues from research, development and sales milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the period of performance. To date, we have determined all milestones are substantive. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

Government grants

Government grants are recognized when there is reasonable assurance that all conditions will be complied with and the grant will be received. As the government grants generally represent subsidies for specified activities, they are recognized when earned as revenue from grants.

Funds received that are not related to research and development expenses that have already been incurred, such as the EUROCALIN grant, are recorded as deferred revenue until such time that the related expenses have been incurred by us or by one of the other members of the EUROCALIN consortium. At the time eligible expenses are incurred, the applicable portion of deferred revenue according to the respective funding rates is recorded as revenue from grants.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, we determine whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, we carry out an evaluation of disclosure requirements and consider possible accruals in the financial statements.

Income taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that its net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce its net deferred tax assets.

We recognize, measure, present and disclose in our financial statements any uncertain tax positions that we have taken, or expect to take on a tax return. We operate in multiple jurisdictions, both within and outside the United States, and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense.

Recently Issued Accounting Pronouncements

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see "Note 2—Summary of Significant Accounting Policies" in our consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, establishes a class of company called an "emerging growth company," which generally is a company whose initial public offering was completed after December 8, 2011 and had total annual gross revenues of less than $1 billion during its most recently completed fiscal year. Additionally, Section 12b-2 of the Exchange Act establishes a class of company called a "smaller reporting company," which generally is a company with a public float of less than $75 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is $0, had annual revenues of less than $50 million during the most recently completed fiscal year for which audited financial statements are available. We currently qualify as both an emerging growth company and a smaller reporting company.

As an emerging growth company and a smaller reporting company, we are eligible to take advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for those classifications, including without limitation the following:

- An emerging growth company is exempt from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and financial statements, commonly known as an "auditor discussion and analysis."
- An emerging growth company is not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders.
- Neither an emerging growth company nor a smaller reporting company is required to comply with the requirement of auditor attestation of management's assessment of internal control over financial reporting, which is required for other public reporting companies by Section 404 of the Sarbanes-Oxley Act.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced disclosure obligations regarding executive compensation in its periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures.
- A company that is either an emerging growth company or a smaller reporting company is eligible for reduced financial statement disclosure in registration statements, which must include two years of audited financial statements rather than the three years of audited financial statements that are required for other public reporting companies. Smaller reporting companies are also eligible to provide such reduced financial statement disclosure in annual reports on Form 10-K.

For as long as we continue to be an emerging growth company and/or a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2019. We will remain a smaller reporting company until we have a public float of $75 million or more as of the last business day of our most recently completed second fiscal quarter. We also expect that we will remain a smaller reporting company for the foreseeable future, and we could retain our smaller reporting company status indefinitely depending on the size of our public float.

Emerging growth companies may elect to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements required by this Item are as set forth in Item 15 beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining “disclosure controls and procedures” as such term is defined in Rule 13a-15(e), under the Securities Exchange Act of 1934, as amended, as well as for establishing and maintaining “adequate internal control over financial reporting” as such term is defined in Rule 13a-15(f). The Company’s system of internal controls over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with generally accepted accounting principles.

Because of the inherent limitations surrounding internal controls over financial reporting, our disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, under the supervision of and with the participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company’s internal control over financial reporting and disclosure controls and procedures as of December 31, 2015. In making this assessment, management used the updated criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment under the COSO Internal Control-Integrated Framework, management believes that, as of December 31, 2015, our internal control over financial reporting is effective**.**

Changes in Internal Control over Financial Reporting

Other than described below, there have been no changes in internal control over financial reporting that occurred during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Pieris had historically been a private company and did not maintain the internal accounting and financial reporting resources necessary to comply with the obligations of a public reporting company, including maintaining effective internal controls over financial reporting. In December 2014, management determined that it had a material weakness on our internal control over financial reporting due to the lack of accounting policies, procedures and accounting personnel.

In response to such material weakness, management hired the appropriate accounting and financial professionals necessary for a public reporting company. The accounting staff has the experience and training necessary to prepare, record and review accounting policies, processes and procedures, particularly revenue recognition, equity related transactions and other complex and/or judgmental areas of accounting. Additionally, we took steps to adopt an internal control infrastructure based on the criteria set forth in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission (2013 framework).

As a result of the remediation efforts completed during 2015, management has determined that as of December 31, 2015, the material weakness has been remediated.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

MANAGEMENT

Directors, Executive Officers and Other Non-Executive Officers

The table below sets forth information about our directors and executive officers:

Name	Age	Position
Stephen S. Yoder	40	Chief Executive Officer, President and Director
Darlene Deptula-Hicks	58	Senior Vice President and Chief Financial Officer
Louis A. Matis	65	Senior Vice President and Chief Development Officer
Chau Khuong (1)(2)(3)	40	Chairman of the Board of Directors
Michael Richman (1)(3)	55	Director
Jean-Pierre Bizzari (2)(3)	61	Director
Steven Prelack (2)	58	Director

(1) Member of the compensation committee
(2) Member of the audit committee
(3) Member of the nominating and corporate governance committee

Business Experience

The following is a brief account of the education and business experience of our current directors and executive officers:

Stephen S. Yoder. Stephen S. Yoder joined Pieris GmbH as Chief Executive Officer in January 2010. Upon the effectiveness of the Acquisition, he joined the Board of Directors of Pieris and was appointed as Chief Executive Officer and President. Prior to joining Pieris GmbH, from July 2003 to December 2010 he led the intellectual property and legal departments at MorphoSys AG, a biotechnology company involved in the development and research of antibodies, as General Counsel. Prior to MorphoSys AG, from September 1999 to June 2003 he worked in several Washington, D.C. law firms, specializing in a life sciences intellectual property practice. Mr. Yoder holds degrees in molecular biology and Spanish from Grove City College and a Juris Doctorate, with honors, from The George Washington University Law School. As an attorney, he is licensed to practice before the United States Patent and Trademark Office, and in the jurisdictions of Maryland and Washington, D.C. We believe that Mr. Yoder adds value to our Board of Directors based on his intimate knowledge of our business plans and strategies of our business and his years of experience in the biotechnology and life sciences industry.

Darlene Deptula-Hicks. Darlene Deptula-Hicks was appointed Chief Financial Officer and Senior Vice President on September 1, 2015. Upon the effectiveness of the Acquisition and until September 2015, she served as our Acting Chief Financial Officer, Secretary and Treasurer of Pieris and provided her services pursuant to a consulting agreement with the financial advisory firm of Danforth Advisors, LLC. From November 2014 until the effectiveness of the Acquisition, Ms. Deptula-Hicks provided financial services relating to the Acquisition to Pieris GmbH. From June 2012 until November 2014, Ms. Deptula-Hicks served as the Executive Vice President and Chief Financial Officer of Microline Surgical, Inc., a surgical instruments and medical devices company. From 2006 to May 2011 Ms. Deptula-Hicks served as Executive Vice President and Chief Financial Officer of iCAD, Inc. (Nasdaq: ICAD), a publicly traded medical device company. From 2002 to 2006 Ms. Deptula-Hicks served as Executive Vice President and Chief Financial Officer of ONI Medical Systems, Inc., a venture capital-backed designer and manufacturer of high-field diagnostic imaging systems for orthopedic applications, and from 1998 to 2001 Ms. Deptula-Hicks was Executive Vice President and Chief Financial Officer of Implant Sciences Corporation (Amex:IMX), an early stage medical device company that had its initial public offering in June of

1999. Prior to 1998, Ms. Deptula-Hicks also held various senior financial and accounting positions at Abiomed, Inc., GCA Corporation, Edwards High Vacuum International and Puritan Bennett Corporation. Ms. Deptula-Hicks also serves on the Board of Directors and as Chair of the Audit Committee of Xenetic Biosciences, Inc. (OTCBB:XBIO) and between 2006 and October 2014 served on the Board of Directors of IMCOR Pharmaceutical Company, Technest Holdings, Inc., and USfalcon. Ms. Deptula-Hicks received her B.S. in accounting from Southern NH University and her MBA from Rivier College.

Louis A. Matis, Ph.D. Louis A. Matis was appointed Senior Vice President and Chief Development Officer in August 17, 2015. Prior to joining Pieris, Dr. Matis served since June 2011 as Executive Director, Strategic Evaluation at Alexion Pharmaceuticals, where he also served from 1993 to 2000, during which time he advanced to the position of Chief Scientific Officer and had a leading role in discovering the first-in-class complement inhibitor monoclonal antibody Soliris® (eculizumab). Before re-joining Alexion in 2011, Dr. Matis served as Chief Executive Officer of CGI Pharmaceuticals, Inc. from 2000 to 2006, and of the Immune Tolerance Institute from 2007 to 2010. From 1977 until joining Alexion in 1993, Dr. Matis held senior research and clinical positions at the National Cancer Institute (the NCI), National Institutes of Health and the FDA Center for Biologics Evaluation and Research. Dr. Matis received a B.A. from Amherst College, an M.D. from the University of Pennsylvania, Perelman School of Medicine, and his clinical training in Internal Medicine at the University of Chicago Hospitals and Clinics, and in Medical Oncology at the NCI. Dr. Matis is the author of over 120 publications in major scientific and medical journals and is a co-inventor on multiple patents.

Chau Khuong. Mr. Khuong joined the Board of Directors of Pieris effective upon the closing of the Acquisition and has served on the supervisory board of Pieris GmbH since May 2014. Mr. Khuong has worked at OrbiMed Advisors LLC since 2003 and is a Private Equity Partner. Mr. Khuong gained experience in start-up operations and business development at Veritas Medicine, Inc. and in basic science research at the Yale School of Medicine and at Massachusetts General Hospital. He currently serves as a director of several public and private companies, including Aerpio Therapeutics, Inspire Medical Systems, Intellia, Nabriva (NASDAQ: NBVR), NextCure, Otonomy (NASDAQ: OTIC), Rempex Pharmaceuticals, ReViral Ltd., and Synlogic. Mr. Khuong holds a B.S. in molecular, cellular and developmental biology with concentration in biotechnology and an MPH with concentration in infectious diseases, both from Yale University. We believe that Mr. Khuong adds value to our Board of Directors due to his experience as an investor, particularly with respect to healthcare companies, and his broad life sciences industry knowledge. He also has extensive experience overseeing the operations and research and development of biotechnology companies.

Michael Richman. Mr. Richman joined the Board of Directors of Pieris effective upon the closing of the Acquisition and has served on the supervisory board of Pieris GmbH since October 2014. He is currently the President and Chief Executive Officer of NextCure, Inc. From 2008 through 2015 Mr. Richman was President and CEO of Amplimmune, Inc., a privately held biologics company focused on cancer and autoimmune diseases which was acquired by Astra Zeneca in 2013. From May 2007 through June 2008, he served as President and Chief Operating Officer of Amplimmune, Inc. Prior to such time, Mr. Richman has gained years of experience working in research, intellectual property and business development capacities in companies such as Chiron Corporation (now Novartis), MedImmune, Inc. (now Astra Zeneca) and MacroGenics. He is a member of the board of directors of Opexa Therapeutics, Inc., a public company, Madison Vaccines, Inc., a private company, and was previously director of Cougar Biotechnology until its acquisition by Johnson & Johnson. Mr. Richman obtained his B.S. in genetics/molecular biology at the University of California at Davis and his M.S.B.A. in international business at San Francisco State University. We believe that Mr. Richman adds value to our Board of Directors due to his extensive experience in mergers and acquisitions, business development and strategic planning for life science companies, as well as executive leadership and management experience.

Jean-Pierre Bizzari, M.D. Dr. Bizzari joined the Board of Directors of Pieris on May 12, 2015. Dr. Bizzari served as Executive Vice-President, Group Head, Clinical Oncology Development at Celgene Corporation, a role he held from October 2008 until his retirement in December 2015. In this position, Dr. Bizzari was responsible for Celgene's clinical development and operations-statistics teams across the U.S., Europe and Asia/Japan, and has overseen the development and approval of a number of leading oncology products including REVLIMID®

(lenalidomide), VIDAZA® (azacitidine), ISTODAX® (romidepsin) and ABRAXANE® (nab-paclitaxel). In addition, he was Chairman of Celgene's hematology oncology development committee and a member of the company's management committee. Prior to his role at Celgene and from 2004 to 2008, Dr. Bizzari was the Vice President, Clinical Oncology Development for Sanofi-Aventis where he oversaw the approval of Eloxatin® (oxaliplatin), Taxotere® (docetaxel) and Elitek® (rasburicase). From 2002 to 2004, he was Vice President, Clinical Development Oncology for Sanofi-Synthelabo and from 1993 to 2002 served in the same role for Rhône-Poulenc Rorer (Aventis). Dr. Bizzari is a member of the Scientific Advisory Board of France's National Cancer Institute and a board member of the EORTC. He is also currently a member of the board of directors of Halozyme Therapeutics, Inc., Celator Pharmaceuticals, Inc., Transgene SA, Items and Onxeo. Dr. Bizzari received his medical degree from the University of Nice (France) and is an oncologist, having trained at La Pitié-Salpêtrière hospital in Paris, followed by training at the Ontario Cancer Institute and McGill Cancer Center. We believe that Dr. Bizzari adds value to our Board of Directors based on his considerable experience in the pharmaceutical industry and his insight on clinical, regulatory and commercial aspects of drug development, particularly in oncology and global drug approval strategy.

Steven Prelack. Mr. Prelack joined the Board of Directors of Pieris effective upon the closing of the Acquisition. Mr. Prelack is the Senior Vice President and Chief Operating Officer of VetCor, which owns and operates veterinary hospitals across the United States, and has served in this position since June 2012. Prior to that time and since May 2010, Mr. Prelack served at VetCor as Senior Vice President of Operations and as Chief Financial Officer. From 2001 until May 2010, he was the Senior Vice President, Chief Financial Officer and Treasurer of VelQuest Corporation, a provider of automated compliance software solutions for the pharmaceutical industry. He is currently a director and audit committee chair of Galectin Therapeutics, Inc., a publicly traded clinical-stage biotechnology company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Mr. Prelack also previously served as director and audit committee chair for BioVex Group, Inc., a clinical-stage biotechnology company focused on the development and future commercialization of targeted treatments for cancer and the prevention of infectious disease, which was sold to Amgen in 2011, and as a director of VelQuest Corporation, OPCAT, Inc. and Foodsafe Solutions, Inc. Mr. Prelack is a Certified Public Accountant, received a B.B.A. degree from the University of Massachusetts at Amherst in 1979 and is a member of the National Association of Corporate Directors. We believe that Mr. Prelack adds value to our Board of Directors due to his extensive executive leadership experience, director experience within the biotechnology sector and his many years serving in senior financial and operational management roles.

Term of Office of Directors

We currently have authorized five directors. In accordance with our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2015, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- the Class I director is Jean-Pierre Bizzari and his term will expire at the annual meeting of stockholders to be held in 2018;
- the Class II directors are Chau Khuong and Steven Prelack, and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- the Class III directors are Stephen S. Yoder and Michael Richman, and their terms will expire at the annual meeting of stockholders to be held in 2017.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that each class will consist of approximately one-third of the directors.

Family Relationships

There are no family relationships among any of our current or former directors or executive officers.

Involvement in Certain Legal Proceedings

None of our directors, executive officers, significant employees, promoters or control persons has been involved in any legal proceeding in the past 10 years that would require disclosure under Item 401(f) of Regulation S-K promulgated under the Securities Act.

Nominations to the Board of Directors

Director candidates are considered based upon various criteria, including without limitation their broad-based business and professional skills and experiences, expertise in or knowledge of the life sciences industry and ability to add perspectives relating to that industry, concern for the long-term interests of our stockholders, diversity, and personal integrity and judgment. Our Board of Directors has a critical role in guiding our strategic direction and overseeing the strategy of our business, and accordingly, we seek to attract and retain highly qualified directors who have sufficient time to engage in the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans.

Committees of the Board of Directors

Our board has established three standing committees—audit, compensation, and nominating and corporate governance—each of which operates under a charter that has been approved by our board. Our board has determined that all of the members of each of the board's three standing committees are independent as defined under the rules of the NASDAQ Capital Market. In addition, all members of the audit committee meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Steven Prelack, Chau Khuong and Jean-Pierre Bizzari. Steven Prelack serves as the chairperson of the committee. All members of our audit committee meet the requirements for

financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Capital Market. Our board of directors has determined that Steven Prelack is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

Compensation Committee

Our compensation committee reviews and approves policies relating to compensation of our officers and directors and oversees our overall compensation structure, policies and programs. The compensation committee reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves the issuance of stock options and other awards under our equity plan. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Michael Richman and Chau Khuong. Michael Richman serves as the chairperson of the committee.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board's responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors.

The members of our nominating and corporate governance committee are Jean-Pierre Bizzari, Mr. Chau Khuong and Michael Richman. Dr. Bizzari serves as the chairperson of the committee.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires directors, executive officers, and persons owning more than 10 percent of a Company's class of equity securities registered under Section 12 of the Exchange Act to file reports on a timely basis on the initiation of their status as a reporting person and any changes with respect to their beneficial ownership of such equity securities with the SEC. Executive officers, directors and greater than 10 percent stockholders are required by SEC regulations to furnish those companies copies of all Section 16(a) forms they file.

Our records reflect all reports which were required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis, except for the following Forms 4 which were inadvertently filed late: Form 4 of Chau Khuong filed on October 30, 2015 reporting a stock option award and Form 4 of Michael Richman filed on October 30, 2015 reporting a stock option award.

CODE OF CONDUCT AND ETHICS

We have adopted a Code of Ethics and Whistler Blower Policy that applies to all of our employees, including our chief executive officer and acting chief financial and accounting officer. The text of the code of conduct and

ethics is posted on our website at www.pieris.com, is filed as an exhibit hereto, and will be made available to stockholders without charge, upon request, in writing to the Corporate Secretary at Pieris Pharmaceuticals, Inc., 255 State St. 9th Floor, Boston, MA 02109. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of The NASDAQ Stock Market.

Item 11. EXECUTIVE COMPENSATION

The following table summarizes the compensation earned in each of our fiscal years ended December 31, 2015 and 2014 by our named executive officers, which consisted of our principal executive officer and our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2015 and were serving as executive officers as of such date. The following table includes compensation earned by Mr. Yoder for services performed for Pieris GmbH prior to that entity becoming our wholly owned subsidiary upon the completion of the Acquisition on December 17, 2014, as well as compensation earned following the closing of the Acquisition. The following table does not include compensation information for the individuals who served as Pieris' executive officers prior to the completion of the Acquisition, as all such individuals tendered their resignations from all such positions with us in connection with and effective as of the closing of the Acquisition and no compensation was earned by or paid to any such individuals for their services as officers of Pieris. We refer to the executive officers listed below as the Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus ($)	Option Awards ($) (3)	All other compensation ($)	Total
Stephen S. Yoder	2015(1)	$375,000	$150,000	$ —	$ 7,370(4)	$ 532,370
Chief Executive Officer	2014(2)	$266,222	$ 54,455	$1,643,005	$ 15,973(4)	$1,979,655
Darlene Deptula-Hicks	2015	$100,000	$ 40,000	$ 812,623	$ 3,013(5)	$ 955,636
Chief Financial Officer						
Louis Matis	2015	$131,250	$140,000	$1,066,220	$ —	$1,337,470
Chief Development Officer						

(1) Mr. Yoder's 2015 salary was paid in euros from January 1, 2015 through June 30, 2015 as he was a resident of Germany at the time. Pieris converted each euro denominated amount into U.S. dollars by multiplying the euro amount by the noon buying rate of €1.00 to U.S. $1.0906 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2015. From the period of July 1, 2015 through December 31, 2015, Mr. Yoder's salary was paid in U.S. dollars.

(2) All compensation received by Pieris GmbH's executive officers is paid in euros. For the purposes of completing this table with respect to compensation paid during the fiscal year ended December 31, 2014, Pieris converted each euro denominated amount into U.S. dollars by multiplying the euro amount by the noon buying rate of €1.00 to U.S. $1.2101 in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York as of December 31, 2014.

(3) These amounts represent the aggregate grant date fair value for the option awards granted during the fiscal years presented, determined in accordance with FASB ASC Topic 718. All awards are recognized in expense over the service period.

(4) Represents compensation paid for a monthly car allowance.

(5) Represents compensation paid for a 401(k) employer contribution.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with our Chief Executive Officer

Pieris GmbH

Stephen S. Yoder serves as the Chief Executive Officer of Pieris GmbH pursuant to a management agreement with Pieris GmbH dated August 30, 2009, as amended on March 12, 2012, or the Yoder AG Agreement. On December 17, 2014 in connection with the Acquisition, the Yoder AG Agreement was amended and restated to have Mr. Yoder continue as the Chief Executive Officer of Pieris GmbH and to provide him with the compensation and benefits set forth in his employment agreement with Pieris, as described below. The Yoder AG Agreement provided for a term of 18 months with the term automatically extending for additional one-year periods. Under the terms of the Yoder AG Agreement, beginning on January 1, 2013, Mr. Yoder received an annual base salary of $266,222 (€220,000). In addition, Mr. Yoder was eligible to receive a bonus for each calendar year during the term in an amount up to $54,455 (€50,000) based upon achievement of certain objectives, each as approved by the supervisory board of Pieris GmbH in consultation with Mr. Yoder. Pursuant to the terms of the Yoder AG Agreement Mr. Yoder was also provided with a car allowance of $1,331 (€1,100) plus value added tax (VAT) per month.

Pieris Pharmaceuticals, Inc.

Stephen S. Yoder serves as our President and Chief Executive Officer pursuant to an employment agreement dated December 17, 2014, or the Yoder Employment Agreement. The Yoder Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Mr. Yoder resigns he shall provide us with at least 90 days' prior written notice. Pursuant to this agreement, Mr. Yoder's annual base salary was increased to $375,000, effective as of the closing of the Acquisition. In addition, Mr. Yoder is eligible to receive an annual discretionary bonus of up to 40% of Mr. Yoder's then-effective annual base salary, based upon achievement of individual and corporate performance objectives as determined by the Board of Directors or a committee thereof.

On the effective date of the Acquisition, Mr. Yoder was granted a stock option to purchase 1,280,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is subject to and governed by the terms of the Pieris Plan and a stock option agreement, which stock option agreement provides for a ten year term, and that (i) 25% of the option vested immediately upon grant and (ii) 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant, subject to Mr. Yoder's continued employment.

Pursuant to the Yoder Employment Agreement, Mr. Yoder is prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chairman of the Board of Directors, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Mr. Yoder to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions extending during the term of the agreement and one year thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Mr. Yoder also agreed to assign certain intellectual property rights to Pieris.

All compensation and benefits to be paid to Mr. Yoder pursuant to the Yoder Employment Agreement other than the equity awards shall be paid to Mr. Yoder through the terms and conditions of the Yoder AG Agreement with Pieris GmbH, as amended and restated, for so long as Mr. Yoder remains employed at Pieris Operatin. Upon termination of the Yoder AG Agreement provided that the Yoder Employment Agreement is still in effect, all compensation shall be paid by Pieris.

Termination for Any Reason

Upon termination of Mr. Yoder for any reason, Mr. Yoder will receive all earned but unpaid salary, any accrued vacation time, any vested benefits he may have under any employee benefit plan and any unpaid expense reimbursement accrued through the date of termination, or the Accrued Obligations.

Termination by us Without Cause or by Executive for Good Reason

If Mr. Yoder's employment is terminated (i) by us without cause or (ii) by him for good reason, then we must pay Mr. Yoder (i) the Accrued Obligations earned through the date of termination, (ii) a lump-sum payment comprised of (a) an amount equal to 12 months of his base salary at the time of his termination, and (b) a pro rata portion of the bonus for the year in which the termination occurs, based on year-to-date performance as determined by the Board of Directors, or a committee thereof, in its sole discretion, and (iii) an amount equal to his health insurance premium, paid directly or as a reimbursement to Mr. Yoder, for up to a maximum of 12 months. Payments under items (i)—(iii) above are sometimes referred to in this section as Severance. All unvested equity awards held by Mr. Yoder will immediately vest in full and become exercisable following termination and any forfeiture restrictions will immediately lapse. The Severance and acceleration of any unvested options is expressly conditioned on Mr. Yoder executing and delivering to Pieris a release of claims.

Chief Financial Officer

Consulting Agreement with Danforth Advisors, LLC

From November 19, 2014 to December 17, 2014, Darlene Deptula-Hicks was engaged pursuant to a consulting agreement with the financial advisory firm Danforth Advisors, LLC, or Danforth, as a financial consultant to Pieris, providing financial services relating to the Acquisition. As of the effectiveness of the Acquisition, she was appointed as the Acting Chief Financial Officer, Secretary and Treasurer of Pieris and continued to provide financial services through the Danforth consulting agreement until August 31, 2015. Pursuant to the Danforth consulting agreement, Pieris paid Danforth $280 per hour for her services. The Danforth consulting agreement was terminated on August 31, 2015. The Danforth consulting agreement contains customary confidentiality obligations which apply to both Danforth and Ms. Deptula-Hicks and extend for a period of five years. We paid Danforth a fee equal to 3.33% of Ms. Deptula-Hicks's starting base salary upon her employment with Pieris pursuant to the terms of the Danforth consulting agreement. Further, we shall indemnify and hold harmless Danforth and Ms. Deptula-Hicks against any claims, losses, damages, or liabilities (or actions in respect thereof) that arise out of or are based on the services performed by Danforth or Ms. Deptula-Hicks for us, except for any such claims, losses, damages or liabilities arising out of the gross negligence or willful misconduct of Danforth or Ms. Deptula-Hicks.

Employment Agreement

Darlene Deptula-Hicks serves as our Senior Vice President and Chief Financial Officer pursuant to an employment agreement dated August 27, 2015, or the Deptula-Hicks Employment Agreement. The Deptula-Hicks Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Ms. Deptula-Hicks resigns, she shall provide us with at least 90 days' written notice. Pursuant to this agreement, Ms. Deptula-Hicks receives a base salary of $300,000 and is eligible to receive an annual discretionary bonus award of up to 40% of her then-current base salary, based upon the achievement of specific individual and/or Company-wide performance goals as determined by the Board or a committee of the Board in its sole discretion.

Ms. Deptula-Hicks is entitled to participate in any employee benefit programs, plans and practices on the same terms as other salaried employees on a basis consistent with the participation of other senior executive officers. In connection with her employment, Ms. Deptula-Hicks was granted a stock option to purchase 450,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is subject to

and governed by the terms of the Pieris Plan and a stock option agreement, which stock option agreement provides for a ten year term, and that (i) 6.25% of the option vested immediately upon grant and (ii) 93.75% of the option shall vest ratably in equal installments each quarter thereafter, subject to Ms. Deptula-Hicks's continued employment. The option is subject to certain restrictions on exercise until the Company's shareholders have approved an increase in the number of shares of common stock authorized under the Plan and if such shareholder approval is not obtained on or prior to September 30, 2016, the option will be cancelled and be of no further effect.

Under the Deptula-Hicks Employment Agreement, Ms. Deptula-Hicks is prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chief Executive Officer, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Ms. Deptula-Hicks to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions extending during the term of the agreement and one year thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Ms. Deptula-Hicks also agreed to assign certain intellectual property rights to Pieris.

Termination for Any Reason

Upon termination of Ms. Deptula-Hicks for any reason, Ms. Deptula-Hicks will be entitled to receive all earned but unpaid salary, any accrued vacation time, any vested benefits she may have under any employee benefit plan and any unpaid expense reimbursement accrued through the date of termination.

Termination by us Without Cause or by Executive for Good Reason

If Ms. Deptula-Hicks's employment is terminated (i) by us without cause or (ii) by her for good reason, then we must pay Ms. Deptula-Hicks (a) an amount equal to twelve months of salary plus the target bonus amount, pro-rated based on the total number of days elapsed in the calendar year as of the termination date if, as of the date of termination, the Company and Ms. Deptula-Hicks were "on target" to achieve all applicable performance goals and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In addition, outstanding equity awards held by Ms. Deptula-Hicks shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Deptula-Hicks Employment Agreement, and any forfeiture restrictions shall immediately lapse with respect to 50% of the then-unvested equity awards.

Chief Development Officer

Dr. Louis Matis serves as our Senior Vice President and Chief Development Officer pursuant to an employment agreement dated July 20, 2015, or the Matis Employment Agreement. The Matis Employment Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Dr. Matis resigns, he shall provide us with at least 90 days' written notice. Pursuant to this agreement, Dr. Matis receives a base salary of $350,000 and is eligible to receive an annual discretionary bonus award of up to 40% of his then-current base salary, based upon the achievement of specific individual and/or Company-wide performance goals as determined by the Board or a committee of the Board in its sole discretion.

Dr. Matis is entitled to participate in any employee benefit programs, plans and practices on the same terms as other salaried employees on a basis consistent with the participation of other senior executive officers. In connection with his employment, Dr. Matis was granted an inducement stock option to purchase 500,000 shares of our common stock with the exercise price being the fair market value at the time of grant. The option is

subject to and governed by a stock option agreement, which provides for a ten year term, and that (i) 25% of the option vests on the one-year anniversary of Dr. Matis's start date and (ii) 75% of the option shall vest ratably in equal installments each quarter thereafter, subject to Dr. Matis's continued employment.

Under the Matis Employment Agreement, Dr. Matis is prohibited during the term of the agreement, subject to certain exceptions, from (i) accepting any other employment or consultancy, (ii) serving on the board of directors or similar body of any other entity, unless approved by the Chief Executive Officer, and (iii) acquiring, assuming or participating in, directly or indirectly, any financial position, investment or interest known by Dr. Matis to be adverse or antagonistic to Pieris, its business or prospects, financial or otherwise, or in any competing business.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions extending during the term of the agreement and one year thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Dr. Matis also agreed to assign certain intellectual property rights to Pieris.

Termination for Any Reason

Upon termination of Dr. Matis for any reason, Dr. Matis will be entitled to receive all earned but unpaid salary, any accrued vacation time, any vested benefits he may have under any employee benefit plan and any unpaid expense reimbursement accrued through the date of termination.

Termination by us Without Cause or by Executive for Good Reason

If Dr. Matis's employment is terminated (i) by us without cause or (ii) by him for good reason, then Dr. Matis will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount, pro-rated based on the total number of days elapsed in the calendar year as of the termination date if, as of the date of termination, the Company and Ms. Deptula-Hicks were "on target" to achieve all applicable performance goals and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In addition, outstanding equity awards held by Dr. Matis shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Matis Employment Agreement, and any forfeiture restrictions shall immediately lapse with respect to 75% of the then-unvested equity awards.

Potential Payments upon Termination or Change in Control

Chief Executive Officer

Under the Yoder Employment Agreement, if Mr. Yoder's employment is terminated (i) by us without cause or (ii) by Mr. Yoder for good reason within 12 months following a change in control, and Mr. Yoder executes and delivers to Pieris a release of claims, then Mr. Yoder shall receive (i) the Accrued Obligations earned through the date of termination, (ii) a lump-sum payment comprised of (a) an amount equal to 12 months of his base salary at the time of his termination, and (b) the target bonus for the year in which the termination occurs, and (iii) an amount equal to his health insurance premium, paid directly or as a reimbursement to Mr. Yoder, for up to a maximum of 12 months. All unvested equity awards will immediately vest in full and become exercisable following termination and any forfeiture restrictions will immediately lapse.

For purposes of the Yoder Employment Agreement, "cause" shall mean the occurrence of any of the following events, as determined by the Board of Directors or a committee designated by the Board of Directors, in its sole discretion: (i) Mr. Yoder's commission of any felony or any crime involving fraud, dishonesty, or moral turpitude under the laws of Germany, the United States or any state thereof; (ii) Mr. Yoder's attempted commission of, or participation in, a fraud against Pieris; (iii) Mr. Yoder's intentional, material violation of any contract or agreement between Mr. Yoder and Pieris or of any statutory duty owed to Pieris; (iv) Mr. Yoder's unauthorized use or disclosure of Pieris' confidential information or trade secrets; or (v) Mr. Yoder's gross misconduct.

For purposes of the Yoder Employment Agreement, "good reason" means Mr. Yoder's resignation from all positions he then holds with Pieris if (i) (a) there is a material diminution in Mr. Yoder's duties and responsibilities with Pieris; (b) there is a material reduction of Mr. Yoder's base salary; provided, however, that a material reduction in Mr. Yoder's base salary pursuant to a salary reduction program affecting all or substantially all of the employees of Pieris and that does not adversely affect Mr. Yoder to a greater extent than other similarly situated employees shall not constitute good reason; or (c) Mr. Yoder is required to relocate Mr. Yoder's primary work location to a facility or location that would increase Mr. Yoder's one-way commute distance by more than 50 miles from Mr. Yoder's primary work location as of immediately prior to such change, (ii) Mr. Yoder provides written notice outlining such conditions, acts or omissions to Pieris within 30 days immediately following such material change or reduction, (iii) such material change or reduction is not remedied by Pieris within 30 days following Pieris' receipt of such written notice and (iv) Mr. Yoder's resignation is effective not later than 30 days after the expiration of such 30 day cure period.

For purposes of the Yoder Employment Agreement, a "change in control" shall be deemed to occur (i) when any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of Pieris representing 50% or more of the total voting power represented by Pieris' then outstanding voting securities (excluding for this purpose any such voting securities held by the Pieris or its affiliates or by any employee benefit plan of Pieris) pursuant to a transaction or a series of related transactions which the Board of Directors does not approve; or (ii) a merger or consolidation of Pieris whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of Pieris outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting power represented by the voting securities of Pieris or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (iii) the sale or disposition by Pieris of all or substantially all of its assets in a transaction requiring stockholder approval.

Chief Financial Officer

If, in connection with a change of control of Pieris, Pieris terminates Ms. Deptula-Hicks's employment without cause or Ms. Deptula-Hicks terminates her employment for good reason, she will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount for the year of termination and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In the case of such a termination in connection with a change in control, outstanding equity awards held by Ms. Deptula-Hicks shall automatically become vested and if, applicable, exercisable, except as otherwise provided in the Deptula-Hicks Employment Agreement, and all forfeiture restrictions shall immediately lapse.

Chief Development Officer

If, in connection with a change of control of Pieris, Pieris terminates Dr. Matis's employment without cause or Dr. Matis terminates his employment for good reason, he will be entitled to receive (a) an amount equal to twelve months of salary plus the target bonus amount for the year of termination and (b) continuation of COBRA health insurance premiums at the Company's then-normal rate of contribution for twelve months. In the case of such a termination in connection with a change in control, outstanding equity awards held by Dr. Matis shall automatically become vested and if, applicable, exercisable and all forfeiture restrictions shall immediately lapse.

For purposes of the Deptula-Hicks Employment Agreement and the Matis Employment Agreement, "Good Reason" means the executive's resignation from all positions he or she then holds with the Company if (i) (A) there is a material diminution in the executive's duties and responsibilities with the Company or in job title; (B) there is a material reduction of the executive's base salary; provided, however, that a material reduction in the executive's base salary pursuant to a salary reduction program affecting all or substantially all of the

employees of the Company and that does not adversely affect the executive to a greater extent than other similarly situated employees shall not constitute Good Reason; or (C) the executive is required to relocate the executive's primary work location to a facility or location that would increase the executive's one-way commute distance by more than fifty (50) miles from the executive's primary work location as of immediately prior to such change, (ii) the executive provides written notice outlining such conditions, acts or omissions to the Company within thirty (30) days immediately following such material change or reduction, (iii) such material change or reduction is not remedied by the Company within thirty (30) days following the Company's receipt of such written notice and (iv) the executive's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

2015 Bonus Payments

On January 24, 2016, our Compensation Committee approved a discretionary cash bonus payments to (i) Mr. Yoder in the amount of $150,000, which was equal to his target bonus amount, (ii) Dr. Matis in the amount of $140,000, which was equal to his target bonus amount and (iii) Ms. Deptula-Hicks in the amount of $40,000, which was equal to her target bonus amount and prorated from her start date in September 2015.

Outstanding Equity Awards at Fiscal Year-End

The table below summarizes the aggregate stock and option awards held by our named executive officers as of December 31, 2015.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Stephen S. Yoder Chief Executive Officer, President	640,000(1)	640,000(1)	$ 2.00	12/17/2024
Darlene Deptula-Hicks Chief Financial Officer	0	450,000(2)	$ 2.80	9/1/2025
Louis Matis Chief Development Officer	0	500,000(3)	$ 3.36	8/17/2025

(1) The option award has a grant date of December 17, 2014 and vests pursuant to the following schedule: 25% of the option vested immediately upon grant on December 17, 2014 and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.

(2) The option award has a grant date of September 1, 2015 and vests pursuant to the following schedule: 6.25% of the option vested immediately upon grant on September 1, 2015 and 93.75% of the option shall vest in equal installments on a quarterly basis beginning on December 31, 2015 and ending on September 1, 2019. The option is subject to certain restrictions on exercise until the Company's shareholders have approved an increase in the number of shares of common stock authorized under the Company's 2014 Employee, Director and Consultant Equity Plan (or successor plan) and if such shareholder approval is not obtained on or prior to September 30, 2016, the option will be cancelled and be of no further effect.

(3) The option award has a grant date of August 17, 2015 and vests pursuant to the following schedule: 25% of the option vests on the one-year anniversary of the grant date and 75% of the option shall vest ratably over three years in equal installments on a quarterly basis beginning on the last day of the next calendar quarter after the date of grant.

Description of Pieris Plan

In December 2014, our Board of Directors and stockholders adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, or the Pieris Plan, which became effective upon closing of the Acquisition. The Pieris Plan is intended to encourage ownership of common stock by our employees and directors and certain of

our consultants in order to attract and retain such people, to induce them to work for the benefit of us and to provide additional incentive for them to promote our success. The Pieris Plan reserves for issuance 4,200,000 shares of our common stock. In addition the Pieris Plan provides for an "evergreen" provision whereby the number of shares of our common stock reserved for issuance under the Pieris Plan shall be automatically increased on January 1 of each of year by the lesser of (i) 1,000,000 shares, (ii) 4% of the number of shares of our common stock outstanding on such date, and (iii) such other amount determined by the administrator. As of the date of this report, options to purchase 2,092,261 shares of our common stock have been issued under the Pieris Plan to our executive officers and directors, and options to purchase 1,801,450 shares have been issued under the Pieris Plan to other employees and consultants. For additional information, see "Item 11. Executive Compensation—Director Compensation" and "Item 11. Executive Compensation—Employment Agreements with our Chief Executive Officer." As a result of such grants, 433,789 shares of our common stock remain available for future issuances under the Pieris Plan.

Pursuant to a Stock Option Agreement with Ms. Deptula-Hicks, we granted her an option to purchase 450,000 shares of our common stock subject to certain restrictions on exercise and subject to the approval of the Company's shareholders of an increase in the number of shares authorized under the Plan to provide sufficient shares for such issuance upon the exercise of such award. If such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and affect. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Plan Types of Awards. The Pieris Plan provides for the granting of incentive stock options, non-qualified stock options, stock grants and other stock-based awards, including restricted stock units.

- *Incentive and Non-Qualified Stock Options*. The plan administrator determines the exercise price of each stock option. The exercise price of a non-qualified stock option may not be less than the fair market value of our common stock on the date of grant. The exercise price of an incentive stock option may not be less than the fair market value of our common stock on the date of grant if the recipient holds 10% or less of the combined voting power of our securities, or 110% of the fair market value of a share of our common stock on the date of grant otherwise.
- *Stock Grants*. The plan administrator may grant stock, including restricted stock, to any participant, which purchase price, if any, may not be less than the par value of shares of our common stock. The stock grant will be subject to the conditions and restrictions determined by the administrator. The recipient of a stock grant shall have the rights of a stockholder with respect to the shares of stock as of the grant date.
- *Stock-Based Awards*. The administrator of the Pieris Plan may grant other stock-based awards, including stock appreciation rights, phantom stock awards and restricted stock units, with terms approved by the administrator, including restrictions related to the awards. The holder of a stock-based award shall not have the rights of a stockholder until shares of our common stock are issued pursuant to such award.

Plan Administration. Our compensation committee is the administrator of the Pieris Plan, except to the extent it delegates its authority to a committee, in which case the committee shall be the administrator. The administrator has the authority to determine the recipients of the awards, the terms of awards, including exercise and purchase price, the number of shares subject to awards, the vesting schedule applicable to awards, the form of consideration, if any, payable upon exercise or settlement of an award and the terms of award agreements for use under the Pieris Plan. In addition, the administrator may amend any term or condition of any outstanding award including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting schedule or extend the expiration date, provided that no such amendment shall impair the rights of a participant without such participant's consent.

Eligibility. The administrator will determine the participants in the Pieris Plan from among our employees, directors and consultants. A grant may be approved in advance with the effectiveness of the grant contingent and effective upon such person's commencement of service within a specified period. No participant may receive awards for more than 1,500,000 shares of our common stock in any fiscal year.

Termination of Service. Unless otherwise provided by the administrator or in an award agreement, upon a termination of a participant's service, all unvested options then held by the participant will terminate and all other unvested awards will be forfeited.

Transferability. Awards under the Pieris Plan may not be transferred except by will or by the laws of descent and distribution, unless otherwise provided by our board in its discretion and set forth in the applicable agreement, provided that no award may be transferred for value.

Adjustment. In the event of a stock dividend, stock split, recapitalization or reorganization or other change in change in capital structure, the administrator will make appropriate adjustments to the number and kind of shares of stock or securities subject to awards.

Corporate Transaction. Upon a merger, consolidation or sale of all or substantially all of our assets, the administrator, or the board of directors of any corporation assuming our obligations, may, in its sole discretion, take any one or more of the following actions pursuant to our plan, as to some or all outstanding awards:

- provide that outstanding options will be assumed or substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;
- provide that the outstanding options must be exercised within a certain number of days, either to the extent the options are then exercisable, or at the administrator's discretion, any such options being made partially or fully exercisable;
- terminate outstanding options in exchange for payment of an amount equal to the difference between (a) the consideration payable upon consummation of the corporate transaction to a holder of the number of shares into which such option would have been exercisable to the extent then exercisable (or, in the administrator's discretion, any such options being made partially or fully exercisable) and (b) the aggregate exercise price of those options; provide that outstanding awards will be assumed or substituted for shares of the successor corporation, become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the corporate transaction; and
- terminate outstanding stock grants in exchange for payment of any amount equal to the consideration payable upon consummation of the corporate transaction to a holder of the same number of shares comprising the stock grant, to the extent the stock grant is no longer subject to any forfeiture or repurchase rights (or, at the administrator's discretion, all forfeiture and repurchase rights being waived upon the corporate transaction).

Amendment and Termination. The Pieris Plan will terminate on December 17, 2024 or at an earlier date by vote of the stockholders or our Board of Directors; provided, however, that any such earlier termination shall not affect any awards granted under the Pieris Plan prior to the date of such termination. The Pieris Plan may be amended by our Board of Directors, except that our Board of Directors may not alter the terms of the Pieris Plan if it would adversely affect a participant's rights under an outstanding stock right without the participant's consent. Stockholder approval will be required for any amendment to the Pieris Plan to the extent such approval is required by law, include the Internal Revenue Code or applicable stock exchange requirements.

Director Compensation

The table below summarizes all compensation earned by each of our non-employee directors for services performed during our fiscal year ended December 31, 2015. Mr. Yoder is not in the table below because he receives no separate compensation for his services as a director of our company, and all of the compensation earned by Mr. Yoder during our 2015 fiscal year as an executive officer of our company is reflected in the Summary Compensation Table above.

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Total ($)
Chau Khuong (1)	$ —	$ —	$41,250(6)	$41,250
Dr. Christina Takke (2)	$ 20,000	—		$20,000
Michael Richman (3)	$ —	—	$38,750(6)	$38,750
Steven Prelack (4)	$ 40,000	—		$40,000
Jean-Pierre Bizzari (5)	$ 23,356	—	$52,185(6)	$75,541

(1) As of December 31, 2015, Chau Khuong held option awards for 50,794 shares at exercise prices ranging from $1.94 to $3.00.
(2) As of December 31, 2015, Dr. Christina Takke held no option awards for shares at an exercise price of $2.00.
(3) As of December 31, 2015, Michael Richman held option awards for 79,535 shares at exercise prices ranging from $1.94 to $3.00.
(4) As of December 31, 2015, Steven Prelack held option awards for 30,000 shares at an exercise price of $2.00.
(5) As of December 31, 2015, Jean-Pierre Bizzari held option awards for 30,000 shares at an exercise price of $2.80.
(6) These amounts represent the aggregate grant date fair value of option awards granted to each director in fiscal year 2015 computed in accordance with FASB ASC Topic 718.

On January 11, 2015, our Board of Directors approved a director compensation policy applicable to our non-employee directors and the policy was amended in January 2016. This policy provides for annual cash compensation of $25,000 for each non-employee member of our Board of Directors. In addition, the chair of our audit committee will receive additional annual cash compensation of $15,000, the chair of our compensation committee will receive additional annual cash compensation of $10,000 and the chair of our nominating and corporate governance committee will receive additional annual cash compensation of $7,500. The policy also provides for annual cash compensation of $7,500 for each of the members of our audit committee, $5,000 for each of the members of our compensation committee and $3,750 for each of the members of our nominating and corporate governance committee.

In addition, the policy provides that each of our non-employee directors will be eligible to receive annual equity awards of 15,000 options, which amount was increased to 20,000 options for 2016, to purchase our common stock, and that upon appointment, new non-employee directors will be eligible to receive an equity award of 30,000 options to purchase our common stock. It is anticipated that all such equity awards will be granted under the Pieris Plan or any other equity compensation plan our Board of Directors and stockholders may approve and adopt in the future. The type of any such award, the amount of shares subject to the award, the vesting schedule and all other terms thereof will be subject to the discretion and approval of our Board of Directors on an annual basis.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth the number of shares of our common stock beneficially owned as of March 20, 2016, by (i) each of our current directors and named executive officers, (ii) all executive officers and directors as a group, and (iii) each person known by us to be the beneficial owner of more than 5% of the outstanding shares

of our common stock. We have determined beneficial ownership in accordance with applicable rules of the SEC, which generally provide that beneficial ownership includes voting or investment power with respect to securities. Except as indicated by the footnotes to the table below, we believe, based on the information furnished to us, that the persons named in the table have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

The information set forth in the table below is based on 39,833,023 shares of our common stock issued and outstanding on of March 20, 2016. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after March 18, 2016. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as otherwise noted in the footnotes below, the address for each person listed in the table below, solely for purposes of filings with the SEC, is c/o Pieris Pharmaceuticals, Inc., 225 State Street, 9th Floor, Boston, Massachusetts 02109.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5%+ Stockholders:		
OrbiMed Private Investments III, LP (1)	7,259,620	18.23%
Tekla Capital Management LLC (2)	3,848,191	9.66%
Lombard Odier Asset Management Corp (3)	2,848,804	7.15%
Global Life Bioventure IV, S.a.r.l (4)	2,483,949	6.24%
Novo Nordisk A/S (5)	2,051,802	5.15%
Directors and Named Executive Officers:		
Stephen S. Yoder (6)	720,000	1.78%
Michael Richman (7)	59,189	*
Chau Khuong (8)	48,571	*
Steven Prelack (9)	17,500	*
Jean-Pierre Bizzari (10)	35,000	*
Darlene Deptula-Hicks (11)	—	—
Louis Matis	—	—
All Current Directors and Executive Officers as a Group (7 persons)	880,260	2.16%

* Less than 1%.

(1) Includes 7,194,222 shares held of record by OrbiMed Private Investments III, LP, or OPI III, and 65,398 shares held of record by OrbiMed Associates III, LP, or Associates III. The address for OPI III and Associates III is 601 Lexington Avenue, 54th Floor, New York, New York. Shares of Pieris are directly owned by OPI III and Associates III. OrbiMed Capital GP III LLC, or GP III, is the sole general partner of OPI III and, as such, may be deemed to indirectly beneficially own the shares held by OPI III. OrbiMed Advisors LLC, or OrbiMed, is the general partner of Associates III and the sole managing member of GP III and, as such, OrbiMed may be deemed to indirectly beneficially own the shares held by OPI III and Associates III. Samuel D. Isaly is the managing member of, and owner of a controlling interest in, OrbiMed. Accordingly, OrbiMed and Mr. Isaly may be deemed to have voting and investment power over the shares held by OPI III and Associates III. GP III, OrbiMed and Mr. Isaly disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

(2) The address for Tekla Capital Management LLC is 100 Federal St., 19th Floor, Boston, MA 02110.

(3) The address for Lombard Odier Asset Management Corp is 452 Fifth Avenue, 25th Floor, New York, NY 10018.

(4) The address for FundsGlobal Life Bioventure IV, S.a.r.l. (“Global Life”) is Amicorp Luxembourg S.A., 11-13, Boulevard de la Foire, L-1528 Luxembourg. Omega Fund IV G.P. Manager, Ltd. (“Omega Ltd”)

serves as the general partner of Omega Fund IV GP, L.P. ("Omega GP"), which serves as the general partner of Omega Fund IV, L.P. ("Omega Fund"), which holds all of the outstanding equity interests in Global Life. Each of Omega Fund, Omega GP and Omega Ltd may be deemed may be deemed to have sole voting power and sole dispositive with respect to the shares, and Richard Lim ("Lim"), Otello Stampacchia ("Stampacchia") and Anne-Mari Paster ("Paster"), the directors of Omega Ltd, may be deemed to have shared voting power and shared dispositive power with respect to these shares. Each of Lim, Stampacchia and Paster may each be deemed to beneficially own the shares held by Global Life and each expressly disclaims beneficial ownership of the Shares except to the extent of his or her pecuniary interest in the Shares.

(5) The address for Novo Nordisk A/S is Novo Allé, 2880 Bagsvaerd, Denmark. Novo Nordisk A/S is a corporation governed by a board of directors comprised of 11 directors. The members of the board of directors disclaim beneficial ownership with respect to such shares, except to the extent of their pecuniary interest therein, if any.

(6) Includes options to purchase 720,000 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 1,052,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.

(7) Includes options to purchase 59,189 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 50,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.

(8) Includes options to purchase 48,571 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 32,500 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.

(9) Includes options to purchase 17,500 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 32,500 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.

(10) Includes options to purchase 35,000 shares of our common stock that are exercisable within 60 days of March 18, 2016, and does not include options to purchase 15,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016.

(11) Does not include options to purchase 450,000 shares of our common stock which have vested but will not be exercisable within 60 days after March 18, 2016.

(12) Does not include options to purchase 500,000 shares of our common stock which have not vested and will not be exercisable within 60 days after March 18, 2016

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2015 with respect to compensation plans under which equity securities of the Company are authorized for issuance. For a description of the terms of the Pieris Plan, please see "Item 11. Executive Compensation—Description of Pieris Plan."

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders	3,157,329	$ 2.16	487,671
Equity compensation plans not approved by security holders	500,000	$ 3.36	—
Total	3,657,329	—	487,671

Stock Option Agreement with Ms. Deptula-Hicks

Pursuant to a Stock Option Agreement with Ms. Deptula-Hicks, dated September 1, 2015, an option for 450,000 shares was granted subject to certain restrictions on exercise and subject to the approval by the Company's shareholders to approve an increase in the number of shares authorized under the Plan to provide for sufficient shares for issuance upon exercise of the option; if such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and affect. This option, therefore, does not have an impact on the remaining shares available for future grants currently authorized under the Plan. The grant has a term of ten years and is subject to a vesting schedule of 6.25% immediately and the remaining 93.75% to vest quarterly equally over the next 4 year period.

Stock Option Agreement with Dr. Matis

Pursuant to a Stock Option Agreement with Dr. Matis, dated August 17, 2015, Dr. Matis was granted an option to purchase 500,000 shares of Common Stock at a price per share of $3.36, as an inducement material to his entering into employment with us. The grant has a term of ten years and is subject to a vesting schedule of 4 years, with 25% of the shares vesting on August 17, 2016 and 6.25% of the shares vesting each quarter thereafter, subject to his continued employment with the Company.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

Pieris (Pieris Pharmaceuticals, Inc., formerly known as Marika Inc.)

Except as described below, in the fiscal years ended December 31, 2014 and December 31, 2015, there has not been, nor is there currently proposed, any transaction to which Pieris is or was a party in which the amount involved exceeds the lesser of $120,000 and 1% of the average of its total assets at year-end for the last two completed fiscal years, and in which any of our current directors, executive officers, holders of more than 5% of any class of our voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

We have entered into indemnification agreements with each of our directors and executive officers. Each of those indemnification agreements is in the form approved by our Board of Directors. Those indemnification agreements require that, under the circumstances and to the extent provided for therein, we indemnify such persons to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by

any such person as a result of such person being made a party to certain actions, suits and proceedings by reason of the fact that such person is or was a director, officer, employee or agent of our company, any entity that was a predecessor corporation of our company or any of our affiliates. The rights of each person who is a party to such an indemnification agreement are in addition to any other rights such person may have under applicable Nevada law, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws, any other agreement, a vote of our stockholders, a resolution adopted by our Board of Directors or otherwise.

On December 17, 2014, we entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 6,779,510 shares of our common stock in a private placement offering conducted through a series of closings occurring on December 17, 18 and 23, 2014, at a purchase price per share of $2.00 and for aggregate gross proceeds to us of $13.56 million, or the Private Placement. After deducting for placement agent and other fees and expenses, the aggregate net proceeds from the Private Placement were $12.04 million. In connection with the Private Placement we received funding from the holders of more than 5% of our common stock as follows: (i) of $495,282 from OrbiMed Private Investments III, LP, or OPI III, (ii) $4,718 from OrbiMed Associates III, LP, an affiliate of OPI III, or Associates III, and (iii) approximately $3.0 million from 1798 Fundamental Strategies Master Fund Ltd., or Fundamental Strategies. After giving effect to the Private Placement and as of April 29, 2015, OPI III and Fundamental Strategies is a holder of more than 5% of the outstanding capital stock of Pieris.

At the closings of the Private Placement the Company issued to the investors and their designees, warrants, or the Placement Warrants, to acquire up to 542,360 shares of its common stock. Each of the Placement Warrants is exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance. Each Placement Warrant entitles the registered holder to purchase one share of our common stock at a price of $2.00 per share, exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance. The number of shares issuable upon exercise of each Placement Warrant is adjustable in the event of stock splits, stock dividends, combinations of shares and similar transactions. Furthermore, if we engage in a merger, sale of substantially all of our assets or similar transaction the holders of more than 50% of the outstanding shares of common stock accept a tender offer, each holder of a Placement Warrant that is outstanding shall have the right to receive the number of shares of the surviving corporation and any additional consideration receivable by a holder of the same number of shares of common stock for which such Placement Warrant is exercisable.

On December 17, 2014, we entered into the Registration Rights Agreement with the investors that participated in the Private Placement. Pursuant to the terms of the Registration Rights Agreement, we agreed to file with the SEC, within 90 days following December 17, 2014, a registration statement to register for resale all of the 6,779,510 shares of our common stock issued in the Private Placement, as well as an additional 20,000,000 shares of our common stock which we issued to former stockholders of Pieris GmbH in connection with the closing of the Acquisition, and an additional 542,360 shares of common stock issuable to holders of the Placement Warrants. We have also agreed to use commercially reasonable efforts to have the registration statement declared effective within 180 days following December 17, 2014. If the registration statement is not declared effective on or before the applicable effectiveness deadline or ceases to be effective during the required effectiveness period, except as permitted under the Registration Rights Agreement, we will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock on every monthly anniversary of such failure and prorated for any portion of a month, until it is cured or all of such selling stockholder's securities to be registered thereunder have been or may be sold without restriction pursuant to Rule 144. Furthermore, if we fail to timely file reports required to be filed by us pursuant to Section 13(a) or 15(d) under the Exchange Act, we will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of the value of such selling stockholder's shares of outstanding common stock. Notwithstanding the foregoing, we will not be obligated to make any such payments with respect to any of the securities to be registered thereunder that we are unable to register due to limits imposed by the SEC's interpretation of Rule 415 promulgated under the Securities Act.

Under the Registration Rights Agreement, subject to exception in certain circumstances or pursuant to the Acquisition, as applicable, we have agreed to keep such registration statement effective until the later of

December 17, 2016 and such time as all of the securities to be registered thereunder have been sold under the registration statement or pursuant to Rule 144 or may be sold without restriction pursuant to Rule 144. If there is not an effective registration statement covering the resale of the securities to be registered thereunder at any time prior to December 17, 2015, then the selling stockholders will have "piggyback" registration rights with respect to any such securities that are not eligible for resale pursuant to Rule 144 without volume or manner of sale restrictions in connection with any other registration statement we determine to file that would permit the inclusion of those shares.

In July 2015, we issued and sold an aggregate of 10,302,736 shares of common stock at a price per share of $2.75 pursuant to a registration statement on Form S-1, for an aggregate purchase price of approximately $28.3 million. As part of the offering, OPI III and Associates III collectively purchased 500,000 shares of our common stock at the offering price of $2.75 per share.

Pieris GmbH

Except as described below and except for employment compensation, since January 1, 2014, there has not been, nor is there currently proposed, any transaction to which it was or is a party in which the amount involved exceeds the lesser of $120,000 and 1% of the average of Pieris GmbH's total assets at year-end for the last two completed fiscal years, and in which any of its directors, executive officers, holders of more than 5% of any class of its voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

In 2001, Pieris GmbH entered into a consulting agreement with Dr. Arne Skerra, who was a member of the its supervisory board, pursuant to which Dr. Skerra provides advice regarding the use of new proteins for the purpose of research and development. For each of the years ended December 31, 2012, December 31, 2013 and December 31, 2014, Pieris GmbH paid Dr. Skerra €20,000 ($24,202) under the consulting agreement.

In July 2007, Pieris GmbH entered into a Research and Licensing Agreement with Technische Universität München, or TUM and the TUM License Agreement. The TUM License Agreement granted certain licenses and protective rights to Pieris GmbH related to Anticalin®-brand drug and lipocalin research and Anticalin technology developed by a research team led by Dr. Arne Skerra, who is employed by TUM as Chair of Biological Chemistry. For these licenses and rights, Pieris GmbH paid TUM €15,000 ($18,152) in 2012 and €50,000 ($60,505) in 2013, as well as additional payments of €102,000 ($123,430) in 2012 and €25,500 ($30,858) in 2013 for the research conducted in subsequent project stages. No payments were made for such licenses and rights or any other payments in 2014.

Pieris GmbH is the project coordinator and a participant of the European Consortium for Anticalin® proteins as next generation high-affinity protein therapeutics, or EUROCALIN, collaborative research project, a drug development collaboration among ten distinct companies and academic institutions across Europe funded in large part by the European Commission under its FP7 HEALTH program pursuant to a Consortium Agreement dated November 21, 2011, or the Consortium Agreement, and the Grant Agreement No. 278408 dated November 21, 2011, or the FP7 Grant Agreement. EUROCALIN received a €6.0 million ($7.3 million) grant from the European Union in 2011. TUM is also a member of the EUROCALIN consortium and is entitled to payments under the FP7 Grant Agreement. Pursuant to the FP7 Grant Agreement, in 2012 and 2013, Pieris GmbH, as project coordinator, paid TUM €62,900 ($76,115) and €65,400 ($79,141), respectively, out of the grant funds. No grant funds were dispensed to TUM in 2014.

In November 2012, Pieris GmbH entered into the 2012 Bridge Loan. In connection with the financing, Pieris GmbH received (i) €492,113 ($595,506) from OPI III, (ii) €4,687 ($5,672) from Associates III, (iii) €421,015 ($509,470) from Gilde Europe Food & Agribusiness Fund B.V., or Gilde, (iv) €219,225 ($265,284) from Coöperatieve AAC LS U.A. (Forbion), or Forbion, (v) €252,173 ($305,154) from The Global Life Science Ventures Funds II GmbH & Co. KG i.L., or Global Life KG, (vi) €196,145 ($237,355) from The Global Life Science Ventures Fund II LP, an affiliate of Global Life KG, or Global Life LP, (vii) €199,606 ($241,543) from

Novo Nordisk A/S, or Novo, and (viii) €164,751 ($199,365) from BioM AG, or BioM. The 2012 Bridge Loan accrued interest at a rate of 12% per year and had a maturity date of December 31, 2013, after which the loan amounts began to accrue interest at a rate of 18% per year. In 2012, Pieris GmbH accrued interest in the amounts of €3,445 ($4,169), €33 ($40), €3,368 ($4,076), €1,461 ($1,768), €1,008 ($1,220), €0 ($0), €1,397 ($1,691) and €1,373 ($1,661) under the loans to OPI III, Associates III, Gilde, Forbion, Global Life KG, Global Life LP, Novo and BioM, respectively. In 2013, Pieris GmbH accrued interest in the amounts of €59,054 ($71,461), €562 ($680), €50,522 ($61,137), €26,307 ($31,834), €30,261 ($36,619), €23,537 ($28,482), €23,953 ($28,986) and €19,770 ($23,924) to OPI III, Associates III, Gilde, Forbion, Global Life KG, Global Life LP, Novo and BioM, respectively. BioM Venture Capital GmbH & Co. KG, or BioM Venture, who, as of the date of execution of the 2012 Bridge Loan was a holder of more than 5% of the outstanding capital stock of Pieris GmbH, is an affiliate of BioM. As of the date of execution of the 2012 Bridge Loan, Forbion was a holder of more than 5% of the outstanding capital stock of Pieris GmbH.

In March 2014, the 2012 Bridge Loan was amended. Pursuant to the terms of the amendment, (i) the outstanding amount under the 2012 Bridge Loan was reduced by a $400,000 payment to the holders under the 2012 Bridge Loan and (ii) the maturity date was extended to December 31, 2015. Due to the extension, interest under the amended facility accrued at a rate of 12% per year. In connection with the amended financing, Pieris GmbH had total repayment amounts due of (i) $98,423 from OPI III, (ii) $937 from Associates III, (iii) $84,203 from Gilde, (iv) $43,845 from Forbion, (v) $50,435 from Global Life KG, (vi) $39,229 from Global Life LP, (vii) $39,921 from Novo, and (viii) $32,950 from BioM. BioM Venture and Forbion, as of the date of execution of the amendment, were holders of more than 5% of the outstanding capital stock of Pieris GmbH. Immediately prior to the 2014 Series C Financing, as defined below, there was €2,000,000 ($2,420,200) outstanding under the 2012 Bridge Loan, as amended. As of December 17, 2014 and pursuant to the terms of the 2014 Series C Financing under which the outstanding indebtedness was converted to equity, there were no amounts outstanding under the 2012 Bridge Loan, as amended.

In April 2014, Pieris GmbH entered into a second bridge loan agreement, or the 2014 Bridge Loan, with certain of its stockholders pursuant to which it received a commitment for financing in the aggregate amount of €2,000,000 ($2,420,200), which loan amounts, if called by Pieris GmbH, would be convertible into shares of Pieris GmbH after the maturity date or upon the occurrence of certain events. The 2014 Bridge Loan included two tranches of available financing: (i) Tranche A of €1,500,000 ($1,815,150) and (ii) Tranche B of €500,000 ($605,050). The Tranche A financing commitment consisted of commitments of (i) €598,400 ($724,124) from OPI III, (ii) €3,751 ($4,539) from Associates III, (iii) €149,705 ($181,158) from Novo, (iv) €126,560 ($153,150) from Global Life KG, (v) €98,440 ($119,122) from Global Life LP, (vi) €225,000 ($272,273) from Gilde, (vii) €97,500 ($117,985) from Forbion, (viii) €150,000 ($181,515) from Baytech Venture Capital GmbH & Co. KG, or Baytech, and (ix) €10,310 ($12,476) from BioM. The Tranche B financing commitment consisted of (i) €199,497 ($241,411) from OPI III, (ii) €1,250 ($1,513) from Associates III, (iii) €49,902 ($60,386) from Novo, (iv) €42,197 ($51,063) from Global Life KG, (v) €32,813 ($39,707) from Global Life LP, (vi) €75,000 ($90,758) from Gilde, (vii) €32,500 ($39,328) from Forbion, (viii) €50,000 ($60,505) from Baytech and (ix) €10,310 ($12,476) from BioM. Forbion, BioM Venture and Baytech, as of the date of execution of the 2014 Bridge Loan, were holders of more than 5% of the outstanding capital stock of Pieris GmbH. In June 2014, Pieris GmbH borrowed 67% of Tranche A, which equals €1,000,000 ($1,210,100). The amount borrowed consisted of funds of (i) €398,993 ($482,821) from OPI III, (ii) €2,501 ($3,026) from Associates III, (iii) €99,803 ($120,772) from Novo, (iv) €84,373 ($102,100) from Global Life KG, (v) €65,627 ($79,415) from Global Life LP, (vi) €150,000 ($181,515) from Gilde, (vii) €65,000 ($78,657) from Forbion, (viii) €100,000 ($121,010) from Baytech, and (ix) €6,873 ($8,317) from BioM. Loan amounts outstanding under the 2014 Bridge Loan accrued interest at a rate of 12% per year and had a maturity date of December 31, 2015, after which the loan amounts would accrue interest at a rate of 18% per year. Immediately prior to the 2014 Series C Financing, as defined below, there was €1,000,000 ($1,210,100) outstanding under the 2014 Bridge Loan. In September 2014 and in connection with the 2014 Series C Financing, the stockholder parties to the 2014 Bridge Loan invested the remaining €1,000,000 ($1,210,100) commitment under the bridge loan in cash directly in the 2014 Series C Financing, including funds of (i) €398,994 ($482,823) from OPI III, (ii) €2,500 ($3,025) from Associates III,

(iii) €99,803 ($120,772) from Novo, (iv) €84,373 ($102,100) from Global Life KG, (v) €65,627 ($79,415) from Global Life LP, (vi) €150,000 ($181,515) from Gilde, (vii) €65,000 ($78,657) from Forbion, (viii) €100,000 ($121,010) from Baytech, and (ix) €6,874 ($8,318) from BioM, which was treated as new investment under the 2014 Series C Financing, or the Convertible Cash Investment. As of December 17, 2014 and pursuant to the 2014 Series C Financing under which the outstanding indebtedness was converted to equity, there were no amounts outstanding under the 2014 Bridge Loan.

On October 10, 2014, Pieris GmbH entered into an investment agreement and consolidated shareholders' agreement, each dated October 10, 2014, pursuant to which (i) the aggregate outstanding amounts under the 2012 Bridge Loan, as amended, and 2014 Bridge Loan of €3,000,000 ($3,630,300) were converted into shares of Series C Preferred Stock of Pieris GmbH and (ii) Pieris GmbH received a cash investment, including the Convertible Cash Investment, in the aggregate amount of €5,970,149 ($7,224,477) in consideration for shares of Pieris GmbH's Series C Preferred Stock, or the 2014 Series C Financing.

The converted bridge loan portion of the 2014 Series C Financing included (a) €2,000,000 ($2,420,200) outstanding under the 2012 Bridge Loan, as amended, including funds of (i) €492,113 ($595,506) from OPI III, (ii) €4,687 ($5,672) from Associates III, (iii) €421,015 ($509,470) from Gilde, (iv) €219,225 ($265,284) from Forbion, (v) €252,173 ($305,155) from Global Life KG, (vi) €196,145 ($237,355) from Global Life LP, (vii) €199,606 ($241,543) from Novo and (viii) €164,751 ($199,365) from BioM and (b) €1,000,000 ($1,210,100) outstanding under the 2014 Bridge Loan including funds of (i) €398,994 ($482,823) from OPI III, (ii) €2,500 ($3,025) from Associates III, (iii) €99,803 ($120,772) from Novo, (iv) €84,373 ($102,100) from Global Life KG, (v) €65,627 ($79,415) from Global Life LP, (vi) €150,000 ($181,515) from Gilde, (vii) €65,000 ($78,657) from Forbion, (viii) €100,000 ($121,010) from Baytech, and (ix) €6,874 ($8,318) from BioM.

The cash investment portion of the 2014 Series C Financing provided for two tranches of available financing. The first tranche consisted of a cash investment of €3,552,646 ($4,299,057) and the second tranche consisted of a cash investment of €1,417,503 ($1,715,320). In addition, the cash investment portion of the 2014 Series C Financing included €1,000,000 ($1,210,100) from the Convertible Cash Investment as described above. In October to November 2014, the first tranche of the 2014 Series C Financing was consummated, consisting of an issuance of an aggregate of 1,629,469 shares of Series C Preferred Stock, including funds of (i) €2,218,972 ($2,685,178) from OPI III, (ii) €19,843 ($24,012) from Associates III, (iii) €150,000 ($181,515) from Gilde, (iv) €65,000 ($79,657) from Forbion, (v) €84,373 ($102,100) from Global Life KG, (vi) €65,627 ($79,415) from Global Life LP, (vii) €99,803 ($120,772) from Novo, (viii) €6,874 ($8,318) from BioM, (ix) €275,000 ($332,778) from Baytech and (x) €1,492,537 ($1,806,119) from Cadila Healthcare Limited, or Zydus. In November to December 2014, the second tranche of the 2014 Series C Financing was consummated, consisting of the issuance of an aggregate of 234,877 shares of Series C preferred stock including funds of €579,861 ($701,690) from Mark N. Tompkins. Forbion, BioM Venture, Baytech and Zydus, as of the date of execution of the 2014 Series C Financing, were holders of more than 5% of the outstanding capital stock of Pieris GmbH.

In the aggregate, as of April 29, 2015, Pieris GmbH has received approximately €51.7 million ($62.6 million) in equity investments from its stockholders as follows: (i) in 2001, seed round financing of €0.6 million ($.7 million); (ii) in 2002, two tranches of Series A financing in an aggregate amount of approximately €12.2 million ($14.8 million); (iii) in 2006, Series A-1 financing of approximately €4.9 million ($5.9 million), (iv) in 2008, two tranches of Series B financing in an aggregate of approximately €25.0 million ($30.3 million) and (v) the 2014 Series C Financing of approximately €9.0 million ($10.9 million). Our stockholders have invested in these activities in the following aggregate amounts: (i) approximately €13.1 million ($15.9 million) from OPI III and Associates III; (ii) approximately €8.0 million ($9.7 million) from Global Life KG and Global Life LP; (iii) approximately €7.9 million ($9.6 million) from Gilde; (iv) approximately €5.4 million ($6.5 million) from Novo; (v) approximately €4.8 million ($5.8 million) from Forbion; (vi) approximately €3.4 million ($4.1 million) from Baytech; (vii) an aggregate of approximately €2.7 million ($3.3 million) from Bio M and BioM Venture, an affiliate of BioM, (viii) approximately €1.5 million ($1.8 million) from Zydus, and (ix) approximately €0.6 million ($0.7 million) from Mark N. Tompkins. Other stockholders invested in aggregate approximately €4.4 million ($5.3 million).

Each of OPI III, Gilde, Forbion, Global Life KG, Global Life LP, Novo, Baytech and Zydus was a holder of more than 5% of the outstanding capital stock of Pieris GmbH prior to the closing of the Acquisition, and each of OPI III, Gilde, Forbion, Global Life KG, Novo, Zydus and Mark N. Tompkins was a holder of more than 5% of the outstanding capital stock of Pieris as of December 17, 2014 giving effect to the Acquisition. After giving effect to the Private Placement and as of April 29, 2015, each of OPI III, Gilde, Global Life KG, Novo, Mark N. Tompkins and Fundamental Strategies is a holder of more than 5% of the outstanding capital stock of Pieris. Former members of the supervisory board of Pieris GmbH are associated with these 5% stockholders as follows: Dr. Michael Sheffery is a Partner Emeritus at OrbiMed Advisors LLC, which is the general partner of Associates III and the sole managing member of OPI III, Dr. Hans A. Küpper is a managing director of The Global Life Sciences Ventures GmbH, which is the general partner of Global Life KG and advisor to Global Life LP, and Edwin de Graaf is the managing director of Glide Healthcare Holding B.V., the parent company of Gilde Agribusiness Management B.V., the manager of Gilde. Further, Chau Khuong, a current member of our Board of Directors and a member of the supervisory board of Pieris GmbH, is also an employee of OrbiMed Advisors LLC. Last, in October 2013, Pieris GmbH entered into a development and license agreement with Zydus for the preclinical development of PRS-110, pursuant to which Pieris GmbH shares certain commercial rights to PRS-110 with Zydus. For more information about the Zydus agreement, see “Item 1. Business—Strategic Partnerships”.

Review, Approval or Ratification of Transactions with Related Persons

Pursuant to the written charter of our audit committee, the audit committee is responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our Board of Directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest. All of the transactions described in this section occurred prior to the adoption of the audit committee charter.

Director Independence

In connection with the closing of the Acquisition, our Board of Directors undertook a review of the composition of our Board of Directors and independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that Chau Khuong, Jean-Pierre Bizzari, Michael Richman and Steven Prelack would qualify as “independent” as that term is defined by NASDAQ Listing Rule 5605(a)(2). Stephen S. Yoder would not qualify as “independent” under applicable NASDAQ Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he currently serves as our Chief Executive Officer. In making such determinations, our Board of Directors considered the relationships that each of our non-employee directors has with our company and all other facts and circumstances deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Subject to some exceptions, NASDAQ Listing Rule 5605(a)(2) provides that a director will only qualify as an “independent director” if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that a director cannot be an “independent director” if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director’s immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director’s immediate family has received more than $120,000 per year in direct compensation from us within the preceding three years, other than for service as a director or benefits under a tax-qualified retirement plan or non-discretionary compensation (or, for a family member, as a non-executive employee); (d) the director or a member of the director’s immediate family is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years; (e) the director or a member of the director’s immediate family is,

or in the past three years has been, employed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director's immediate family is an executive officer, partner or controlling stockholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or $200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs). Additionally, in order to be considered an independent member of an audit committee under Rule 10A-3 of the Exchange Act, a member of an audit committee may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other committee of the Board of Directors, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the applicable company or any of its subsidiaries or otherwise be an affiliated person of the applicable company or any of its subsidiaries.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Effective on December 17, 2014, the Company dismissed Harris & Gillespie CPA'S PLLC, or Harris & Gillespie, as our independent registered public accounting firm engaged to audit our financial statements. On January 11, 2015, the Audit Committee engaged Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or E&Y, as the Company's new independent registered public accounting firm to act as the principal accountant to audit the Company's financial statements.

The following table presents fees for professional audit services rendered by E&Y for the audit of the Company's annual financial statements for the years ended December 31, 2015 and December 31, 2014, and fees billed for other services rendered by E&Y during those periods.

	2015	2014
Audit fees: (1)	$396,873	$320,331
Audit related fees: (2)	5,104	5,855
Tax fees:	—	—
All other fees:	—	—
Total	$401,977	$326,186

(1) Audit fees consisted of audit work performed on the annual financial statements, review of quarterly financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as the provision of consents in connection with the filing of registration statements, Current Reports on Form 8-K and related amendments and statutory audits.

(2) Audit related fees consisted principally of fees relating to an audit for Pieris GmbH regarding the FP7 Grant Agreement, which is described in more detail under "Item 13. Certain Relationships and Related Transactions, and Director Independence."

None of the services set forth above in the category audit related fees were approved by the Audit Committee pursuant to Rule 2-01(c)(7)(i)(C) (relating to the approval of a de minimis amount of non-audit services after the fact but before completion of the audit), as all such services were performed by E&Y for Pieris GmbH prior to the engagement of E&Y by the Company and prior to the formation of the Audit Committee in December 2014.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. Audit services include audit work performed on the annual financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. Audit-Related services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. Tax services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. Other Fees are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget at year end by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

Item 15. **EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Item 15(a). The following documents are filed as part of this annual report on Form 10-K:

Item 15(a)(1) and (2) See "Index to Consolidated Financial Statements" on page F-1 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
2.1	Acquisition Agreement, dated as of December 17, 2014, by and among the Registrant, Pieris AG and the former stockholders of Pieris AG named therein		Form 8-K (Exhibit 2.1)	December 18, 2014	333-190728
3.1	Amended and Restated Articles of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	December 18, 2014	333-190728
3.2	Amended and Restated Bylaws of the Registrant		Form 8-K (Exhibit 3.2)	December 18, 2014	333-190728
4.1	Form of Common Stock certificate		Form 8-K (Exhibit 4.1)	December 18, 2014	333-190728
4.2	Form of Common Stock certificate	*			
10.1	2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.1)	December 18, 2014	333-190728
10.2	Form of Stock Option Award Agreement under the Registrant's 2014 Employee, Director and Consultant Equity Incentive Plan	#	Form 8-K (Exhibit 10.2)	December 18, 2014	333-190728
10.3	Collaboration Agreement by and between Pieris AG and Allergan Sales, LLC, dated as of August 21, 2009	±	Form 8-K (Exhibit 10.3)	December 18, 2014	333-190728
10.4	Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of September 24, 2010	±	Form 10-K (Exhibit 10.4)	March 30, 2014	333-190728
10.5	First Letter Agreement to Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur SA, dated as of February 20, 2013	±	Form 8-K (Exhibit 10.5)	December 18, 2014	333-190728
10.6	Side Agreement to the Collaboration and License Agreement by and among Pieris AG, Sanofi-Aventis and Sanofi-Pasteur Inc., dated as of January 19, 2015	±	Form S-1 (Exhibit 10.6)	February 2, 2015	333-202123
10.7	Collaboration Research and Technology Licensing Agreement by and between Pieris AG and Daiichi Sankyo Company Limited, dated as of May 31, 2011	±	Form 10-K (Exhibit 10.7)	March 30, 2014	333-190728
10.8	Development and License Agreement by and between Pieris AG and Cadila Healthcare Limited, dated as of October 7, 2013	±	Form 10-K (Exhibit 10.8)	March 30, 2014	333-190728

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.9	Joint Development and License Agreement by and between Pieris AG and Stelis BioPharma Private Limited, dated as of November 21, 2013	±	Form 10-K (Exhibit 10.9)	March 30, 2014	333-190728
10.10	Research and Licensing Agreement by and between Pieris AG and Technische Universität München, dated as of July 26, 2007	±	Form 10-K (Exhibit 10.10)	March 30, 2014	333-190728
10.11	Research Collaboration and License Agreement by and among the Registrant, Pieris GmbH, Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd., dated as of December 8, 2015	*@			
10.12	Form of Indemnification Agreement by and between the Registrant and each of its current directors and executive officers	#	Form 8-K (Exhibit 10.10)	December 18, 2014	333-190728
10.13	Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of August 30, 2009	#	Form 8-K (Exhibit 10.11)	December 18, 2014	333-190728
10.14	Amendment to Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of March 12, 2012	#	Form 8-K (Exhibit 10.12)	December 18, 2014	333-190728
10.15	Amended and Restated Management Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.13)	December 18, 2014	333-190728
10.16	Acknowledgement and Waiver Agreement by and between Pieris AG and Stephen S. Yoder, dated as of December 12, 2014	#	Form 8-K (Exhibit 10.14)	December 18, 2014	333-190728
10.17	Employment Agreement by and between the Registrant and Stephen S. Yoder, dated as of December 17, 2014	#	Form 8-K (Exhibit 10.15)	December 18, 2014	333-190728
10.18	Management Agreement by and between Pieris AG and Claus Schalper, dated as of February 6, 2008	#	Form 8-K (Exhibit 10.16)	December 18, 2014	333-190728
10.19	Consulting Agreement by and between Pieris AG and Claus Schalper, dated as of July 9, 2013	#	Form 8-K (Exhibit 10.17)	December 18, 2014	333-190728
10.20	Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of June 26, 2013	#	Form 8-K (Exhibit 10.18)	December 18, 2014	333-190728
10.21	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of January 28, 2014	#	Form 8-K (Exhibit 10.19)	December 18, 2014	333-190728
10.22	Amendment to Employment Agreement by and between Pieris AG and Dr. Ulrich Moebius, dated as of October 21, 2014	#	Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728
10.23	Management Agreement by and between Pieris AG and Dr. Laurent Audoly, dated as of May 18, 2010	#	Form 8-K (Exhibit 10.20)	December 18, 2014	333-190728
10.24	Consulting Agreement by and between Pieris AG and Danforth Advisors, LLC, effective as of November 19, 2014	#	Form 8-K (Exhibit 10.22)	December 18, 2014	333-190728

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.25	Employment Agreement by and between the Registrant and Darlene Deptula-Hicks, dated as of August 27, 2015	#	Form 10-Q (Exhibit 10.2)	November 11, 2015	001-37471
10.26	Employment Agreement by and between the Registrant and Louis A. Matis, M.D., dated as of July 20, 2015	#	Form 10-Q (Exhibit 10.1)	November 11, 2015	001-37471
10.27	Lease Agreement by and between Pieris AG and Födergesellschft IZB mbH, dated as of May 4, 2011		Form 8-K (Exhibit 10.23)	December 18, 2014	333-190728
10.28	Agreement of Sublease by and between Berenberg Capital Markets LLC and the Registrant, dated as of August 27, 2015		Form 10-Q (Exhibit 10.3)	November 11, 2015	001-37471
10.29	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholder parties listed therein, dated as of November 12, 2012		Form 8-K (Exhibit 10.24)	December 18, 2014	333-190728
10.30	Amendment to Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed therein, dated as of March 4, 2014		Form 8-K (Exhibit 10.25)	December 18, 2014	333-190728
10.31	Participation Agreement (silent partnership agreement) between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated May 13, 2003		Form 8-K (Exhibit 10.26)	December 18, 2014	333-190728
10.32	Repayment Agreement by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of April 3, 2014		Form 8-K (Exhibit 10.27)	December 18, 2014	333-190728
10.33	Settlement Agreement (Accelerated Repayment Agreement) by and between Pieris AG and tbg Technologie-Beteiligungs-Gesellschaft mbH, dated as of December 11, 2014		Form 8-K (Exhibit 10.28)	December 18, 2014	333-190728
10.34	Convertible Bridge Loan Agreement by and among Pieris AG and the Stockholders listed on Exhibit A thereto, dated as of April 14, 2014		Form 8-K (Exhibit 10.29)	December 18, 2014	333-190728
10.35	Consolidated Shareholders' Agreement 2014, Pieris AG, Freising, Germany, by and among Pieris AG and the Stockholders party thereto, dated October 10, 2014		Form 8-K (Exhibit 10.30)	December 18, 2014	333-190728
10.36	Investment Agreement, Pieris AG, Freising, Germany, by and among Pieris AG, Stephen Yoder and the Existing Shareholders party thereto, dated October 10, 2014		Form 8-K (Exhibit 10.31)	December 18, 2014	333-190728
10.37	Agreement, by and among Pieris AG and the Stockholders party thereto, dated December 5, 2014		Form 8-K (Exhibit 10.32)	December 18, 2014	333-190728
10.38	Split-Off Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014		Form 8-K (Exhibit 10.33)	December 18, 2014	333-190728
10.39	General Release Agreement, by and among the Registrant, Marika Enterprises Inc. and Aleksandrs Sviks, dated December 17, 2014		Form 8-K (Exhibit 10.34)	December 18, 2014	333-190728

Exhibit Number	Exhibit Description		Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
10.40	Form of Securities Purchase Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the Purchasers		Form 8-K (Exhibit 10.1)	December 23, 2014	333-190728
10.41	Form of Registration Rights Agreement, dated December 17, 2014, by and among Pieris Pharmaceuticals, Inc. and the investors party thereto		Form 8-K (Exhibit 10.2)	December 23, 2014	333-190728
10.42	Form of Warrant to Purchase Common Stock, dated December 17, 2014, issued by Pieris Pharmaceuticals, Inc.		Form 8-K (Exhibit 10.3)	December 23, 2014	333-190728
14.1	Corporate Code of Ethics and Conduct and Whistleblower Policy		Form 10-K (Exhibit 14.1)	March 30, 2014	333-190728
21.1	List of Subsidiaries				
31.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*			
31.2	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes—Oxley Act of 2002	*			
32.1	Certification of Stephen S. Yoder, Chief Executive Officer and President, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350	**			
32.2	Certification of Darlene Deptula-Hicks, Acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes—Oxley Act of 2002, 18 U.S.C. Section 1350	**			
101.INS	XBRL Instance Document	*			
101.SCH	XBRL Taxonomy Extension Schema Document	*			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	*			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	*			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	*			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	*			

* Filed herewith
** Furnished herewith

± Confidential treatment received as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.
@ Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC
# Indicates a management contract or compensatory plan

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PIERIS PHARMACEUTICALS, INC.

Date: March 23, 2016

By: /s/ Stephen S. Yoder
Stephen S. Yoder
Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signature	Title	Date
/s/ Stephen S. Yoder Stephen S. Yoder	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2016
/s/ Darlene Deptula-Hicks Darlene Deptula-Hicks	Chief Financial Officer, Secretary and Treasurer *(Principal Financial and Accounting Officer)*	March 23, 2016
/s/ Chau Khuong Chau Khuong	Chairman of the Board of Directors	March 23, 2016
/s/ Jean-Pierre Bizzari Jean-Pierre Bizzari	Director	March 23, 2016
/s/ Michael Richman Michael Richman	Director	March 23, 2016
/s/ Steven Prelack Steven Prelack	Director	March 23, 2016

PIERIS PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Pieris Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Pieris Pharmaceuticals, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pieris Pharmaceuticals, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Dr. Napolitano
Wirtschaftsprüfer
[German Public Auditor]

/s/ Christ
Wirtschaftsprüfer
[German Public Auditor]

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Munich, Germany
March 23, 2016

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 29,349,124	$ 18,474,211
Prepaid expenses and other current assets	2,311,385	1,331,214
Total current assets	31,660,509	19,805,425
Property and equipment, net	2,162,771	2,052,221
Other non-current assets	126,781	—
Total assets	$ 33,950,061	$ 21,857,646
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade accounts payable	$ 1,058,536	$ 1,260,015
Accrued expenses and other current liabilities	1,739,380	986,620
Bank loan, including accrued interest, current portion	—	1,270,605
Total current liabilities	2,797,916	3,517,240
Accrued expenses and other non-current liabilities	23,852	333,988
Total liabilities	2,821,768	3,851,228
Stockholders' equity:		
Common stock, $0.001 par value per share, 300,000,000 shares authorized and 39,833,023 and 29,279,522 shares issued and outstanding at December 31, 2015 and 2014	39,833	29,280
Additional paid-in capital	112,226,723	84,627,283
Accumulated other comprehensive loss	(1,272,574)	(843,097)
Accumulated deficit	(79,865,689)	(65,807,048)
Total stockholders' equity	31,128,293	18,006,418
Total liabilities and stockholders' equity	$ 33,950,061	$ 21,857,646

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2015	2014
Revenue	$ 2,931,931	$ 5,365,054
Operating expenses		
Research and development	8,244,751	5,600,421
General and administrative	8,368,215	6,962,891
Total operating expenses	16,612,966	12,563,312
Loss from operations	(13,681,035)	(7,198,258)
Interest expense, net	(184,645)	(2,654,727)
Other income/(expense), net	10,905	3,003
Loss before income taxes	(13,854,775)	(9,849,982)
Provision/(benefit) for income tax	203,866	(18)
Net Loss	$(14,058,641)	$ (9,849,964)
Net loss per share		
Basic and diluted	$ (0.41)	$ (0.71)
Weighted average number of common shares outstanding		
Basic and diluted	34,392,636	13,872,390

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years ended December 31,	
	2015	2014
Net loss	$14,058,641	$9,849,964
Other comprehensive (loss)/income components:		
Foreign currency translation	(429,477)	113,176
Total other comprehensive (loss)/income	(429,477)	113,176
Comprehensive loss	$14,488,118	$9,736,788

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common shares						
	No. of shares	Share capital	Additional paid-in capital	Receivable from issuance of shares	Accumulated other comprehensive loss	Accumulated deficit	Total equity
Balance as of January 1, 2014	11,828,975	$11,829	$ 57,608,336	$ (121,801)	$ (956,273)	$(55,957,084)	$ 585,007
Net loss	—	—	—	—	—	(9,849,964)	(9,849,964)
Foreign currency translation adjustment	—	—	—	—	113,176	—	113,176
Beneficial conversion feature	—	—	2,236,583	—	—	—	2,236,583
Series C share conversion	5,008,870	5,009	4,254,096	121,801	—	—	4,380,906
Issuance of series C cash shares net $100,820 in offering costs	5,662,167	5,662	7,336,414	—	—	—	7,342,076
Issuance of Common Stock net $1,595,832 in offering costs	6,779,510	6,780	11,956,408	—	—	—	11,963,188
Stock based compensation expense	—	—	571,382	—	—	—	571,382
Issuance of warrants	—	—	664,064	—	—	—	664,064
Balances as of December 31, 2014	29,279,522	29,280	84,627,283	—	(843,097)	(65,807,048)	18,006,418
Net loss	—	—	—	—	—	(14,058,641)	(14,058,641)
Foreign currency translation adjustment	—	—	—	—	(429,477)	—	(429,477)
Stock based compensation expense	—	—	1,164,633	—	—	—	1,164,633
Issuance of restricted shares	150,000	150	446,250	—	—	—	446,400
Issuance of consulting shares	95,765	95	224,905	—	—	—	225,000
Issuance of Common Stock net $2,568,565 in offering costs	10,302,736	10,303	25,753,657	—	—	—	25,763,960
Options exercised	5,000	5	9,995	—	—	—	10,000
Balance as of December 31, 2015	39,833,023	$39,833	$112,226,723	$ —	$ (1,272,574)	$(79,865,689)	$ 31,128,293

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2015	2014
Operating activities:		
Net loss	$(14,058,641)	$ (9,849,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	307,906	366,979
Non-cash interest expense	—	2,589,025
Stock-based compensation	1,164,633	571,382
Non-cash restricted shares	446,400	—
Non-cash consulting shares	225,000	—
Warrants issued in Private Placement	—	664,064
Changes in operating assets and liabilities:		
Restricted cash	—	70,026
Trade accounts receivable	—	465,385
Prepaid expenses and other assets	(1,256,151)	(921,587)
Trade accounts payable	(90,924)	1,115,987
Accrued expenses and other liabilities	556,297	(136,997)
Net cash used in operating activities	(12,705,480)	(5,065,700)
Investing activities:		
Purchase of property and equipment	(620,747)	(267,406)
Net cash used in investing activities	(620,747)	(267,406)
Financing activities:		
Proceeds from exercise of options	10,000	—
Issuance of Common Stock, net of issuance costs	25,763,960	11,963,188
Issuance of Preferred Stock—series C, net of issuance costs	—	7,342,076
Proceeds from convertible stockholder loan	—	1,210,100
Repayment of debt	(1,157,940)	(181,515)
Net cash provided by financing activities	24,616,020	20,333,849
Effect of exchange rate change on cash and cash equivalents	(414,880)	(215,914)
Net increase in cash and cash equivalents	10,874,913	14,784,829
Cash and cash equivalents at beginning of year	18,474,211	3,689,382
Cash and cash equivalents at end of year	$ 29,349,124	$18,474,211
Supplemental cash flow disclosures:		
Cash paid for interest	$ 206,269	$ 71,757
Cash paid for income taxes	$ 203,866	$ —
Noncash investing and Financing Activities:		
Conversion from debt to equity	$ —	$ 4,380,906

The accompanying notes are an integral part of these consolidated financial statements.

PIERIS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Corporate Information

Pieris Pharmaceuticals, Inc. was founded in May 2013 and is a holding company. On December 17, 2014 Pieris Pharmaceuticals GmbH ("Pieris GmbH") (formerly Pieris AG, a German company which was founded in 2001 by Prof. Dr. Arne Skerra, Professor at the Technical University of Munich, Germany, and Claus Schalper) became a wholly owned subsidiary of Pieris Pharmaceuticals, Inc., which was previously named Marika Inc. pursuant to a share exchange transaction (the "Acquisition"). For further information on the Acquisition refer to Note 3 *Acquisition*. The registered office of Pieris Pharmaceuticals, Inc. and the corporate headquarter is located in Boston, MA and the research facility of Pieris GmbH is located in Freising-Weihenstephan, Germany. Pieris Australia Pty Ltd., a wholly owned subsidiary of Pieris GmbH, was formed on February 14, 2014 to conduct research and development in Australia.

Effective as of August 26, 2015 and with notification from the Amtsgericht München as of September 29, 2015 Pieris AG was transformed to Pieris GmbH as a result of a change in the legal entity, Pieris Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively "Pieris" or the "Company") is a clinical-stage biopharmaceutical company that discovers and develops Anticalin® based drugs to target validated disease pathways in a unique and transformative way.

The Company's pipeline includes, among other programs, an immuno-oncology multi-specific tailored for the tumor micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia.

The Company's core Anticalin® technology and platform was developed in Germany, and the Company has partnership arrangements with major multi-national pharmaceutical companies headquartered in the U.S., Europe and Japan and with regional pharmaceutical companies headquartered in India.

2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying consolidated financial statements of Pieris Pharmaceuticals, Inc. and its wholly owned subsidiaries were prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The consolidated financial statements include the accounts of all subsidiaries. All intercompany balances and transactions have been eliminated.

Reclassifications

For comparability purposes, certain prior period amounts in the consolidated financial statements have been reclassified to conform to the current period's presentation within the consolidated balance sheets and consolidated statements of cash flows.

Use of Estimates

The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates are used for, but are not limited to, revenue recognition, deferred tax assets, liabilities and valuation allowances, fair value of stock options and various accruals. Management evaluates its estimates on an ongoing basis. Actual results and outcomes could differ materially from management's estimates, judgments and assumptions.

Foreign Currency Translation

The financial statements of Pieris' foreign subsidiaries are translated from local currency into reporting currency, which is U.S. dollars, using the current exchange rate at the balance sheet date for assets and liabilities, and the average exchange rate prevailing during the period for revenues and expenses. The functional currency for Pieris' foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive loss within stockholders' equity.

Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as other income (expense), net in the consolidated statements of operations.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash on deposit in banks and other cash invested temporarily in money-market funds that are highly liquid and have an original maturity of less than 90 days at the date of purchase.

The Company held $17,302 in restricted cash as of December 31, 2015. There was no restricted cash as of December 31, 2014. Such bank balances in 2015 related to prepayments received by the Company pursuant to EU grants under the EUROCALIN program (see Note 4 *Revenue*). These amounts were restricted to cover future obligations to members of the EUROCALIN consortium; they were not available for use by the Company.

Fair Value Measurement

ASC Topic 820 *Fair Value Measurement* defines fair value as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants at the measurement date. Pieris applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 utilizes quoted market prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

Cash equivalents recorded by Pieris consist of highly liquid money market funds and are measured at fair value on a recurring basis. These funds are classified as Level 1 because they are valued using quoted prices for the periods ended December 31, 2015 and December 31, 2014. The carrying amounts of zero and $4.8 million as of December 31, 2015 and December 31, 2014, respectively, equal the fair value of the cash equivalents.

The Company's debt instruments are classified as Level 2. The fair value of these instruments was determined using the discounted cash flow method based on contractual cash flows and the current rate at which debt with similar terms could be issued. There are no remaining debt instruments as of December 31, 2015. The fair values for these debt instruments approximated carrying values as of December 31, 2014.

All of other current assets and current liabilities on our consolidated balance sheets approximate their respective carrying amounts.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject Pieris to concentrations of credit risk include cash and cash equivalents and trade accounts receivable. Pieris maintains cash and cash equivalents with various major financial institutions. Pieris maintains deposits and owns money market funds only in highly rated financial institutions to minimize the credit risk from the financial institutions. There were no money market funds held at December 31, 2015. Management periodically reviews the credit standing of these financial institutions and believes that Pieris is not exposed to significant credit risk from the institutions in which those deposits are held and through which money-market funds are owned at December 31, 2014.

As of December 31, 2015 and December 31, 2014, respectively, Pieris has no trade accounts receivable. See Note 4 *Revenue*, for additional information regarding Pieris's collaboration agreements.

Pieris relies on third parties to conduct preclinical and clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Pieris may not be able to obtain regulatory approval for Pieris´s drug candidates and Pieris's business could be substantially impacted. Furthermore, Pieris is exposed to the risks associated with third parties formulating and manufacturing its preclinical and clinical drug supplies and any approved product candidates. The development and commercialization of any of its drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide Pieris with sufficient quantities of such drug candidate or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements and prices.

In line with such third-party risk, Pieris depends significantly on the Research and Licensing Agreement (or the "TUM License Agreement") with Technische Universität München "TUM" or "Technical University Munich"), under which certain intellectual property rights are exclusively licensed to Pieris. In the event that the TUM License Agreement is terminated by TUM, Pieris would be significantly hampered in its efforts to develop and commercialize, as well as to sub-license, the drug candidates covered by such exclusive license.

Trade Accounts Receivable

Trade accounts receivable are recorded net of allowances for doubtful accounts and represent amounts due from third parties and collaboration partners. Management monitors and evaluates collectability of receivables on an ongoing basis and considers whether an allowance for doubtful accounts is necessary. Management determined that no such reserve is needed as of December 31, 2015 and 2014 as there were no accounts receivables on the consolidated balance sheets. Historically, Pieris has not had collectability issues with third parties and collaboration partners.

Property and Equipment

Property and equipment are recorded at acquisition cost, less accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the remaining estimated useful lives of the assets. Maintenance and repairs to these assets are charged to expenses as occurred. The estimated useful life of the different groups of property and equipment is as follows:

Asset Classification	Estimated useful life (in years)
Leasehold improvements	shorter of useful life or remaining life of the lease
Laboratory equipment	1 - 14
Office and computer equipment	1 - 15

Impairment of Long-lived Assets

Pieris reviews its long-lived assets to be held and used for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Pieris evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Pieris believes that, as of each of the balance sheets presented, none of Pieris' long-lived assets were impaired.

Revenue Recognition

Pieris has entered into several licensing and development agreements with collaboration partners for the development of Anticalin® therapeutics against a variety of targets in diseases and conditions. The terms of these agreements contain multiple elements and deliverables, which may include (i) licenses, or options to obtain licenses, to Pieris's Anticalin technology and (ii) research activities to be performed on behalf of the collaborative partner. Payments to Pieris under these agreements may include upfront fees (which include license and option fees), payments for research activities, payments based upon the achievement of certain milestones and royalties on product sales. There are no performance, cancellation, termination or refund provisions in any of the arrangements that could result in material financial consequences to Pieris. Pieris follows the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* and ASC Topic 605-28, *Revenue Recognition—Milestone Method* in accounting for these agreements.

Multiple-Element Arrangements

When evaluating multiple-element arrangements, Pieris identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the collaborator or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units of accounting. Pieris has used best estimate of selling price methodology to estimate the selling price for licenses and options to acquire additional licenses to its proprietary technology because Pieris does not have Vendor Specific Objective Evidence or Third Party Evidence of selling price for these deliverables. To determine the estimated selling price of a license to its proprietary technology, Pieris considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements, terms of previous collaborative agreements, similar agreements entered into by third parties, market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating Pieris's best estimate of selling price, Pieris evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

Pieris typically receives upfront, nonrefundable payments when licensing its intellectual property in conjunction with a research and development agreement. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research capabilities of the partner and the availability of Anticalin® technology research expertise in the general marketplace.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, Pieris generally recognizes revenue attributable to the license on a straight-line basis over Pieris's contractual or estimated performance period, which is typically the term of

Pieris's research and development obligations. When management believes the license to its intellectual property has stand-alone value, Pieris recognizes revenue attributed to the license upon delivery. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue Pieris records in future periods.

The accounting treatment for options granted to collaborators is dependent upon the nature of the option granted to the collaborative partner. Options are considered substantive if, at the inception of an agreement, Pieris is at risk as to whether the collaborative partner will choose to exercise the options to secure additional licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

In arrangements where options to obtain additional licenses are considered substantive, Pieris determines whether the optional licenses are priced at a significant and incremental discount. If the prices include a significant and incremental discount, the option is considered a deliverable in the arrangement. However, if not priced at a discount, the elements included in the arrangement are considered to be only the non-contingent elements. When a collaborator exercises an option to acquire an additional license, the exercise fee that is attributed to the additional license and any incremental discount allocated at inception are recognized in a manner consistent with the treatment of up-front payments for licenses (*i.e.*, license and research services). In the event an option expires un-exercised, any incremental discounts deferred at the inception of the arrangement are recognized into revenue upon expiration. For options that are non-substantive, the additional licenses to which the options pertain are considered deliverables upon inception of the arrangement, and Pieris applies the multiple-element revenue recognition criteria to determine accounting treatment. All of Pieris's agreements with options have been determined to include substantive options.

Payments or reimbursements resulting from Pieris's research and development efforts in multi-element arrangements in which Pieris's research and development efforts are considered deliverable are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

Milestone Payments and Royalties

At the inception of each agreement that includes milestone payments, Pieris evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. Pieris evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Pieris aggregates milestones into four categories (i) research milestones, (ii) development milestones, (iii) commercial milestones and (iv) sales milestones. Research milestones are typically achieved upon reaching certain success criteria as defined in each agreement related to developing an Anticalin® protein against the specified target. Development milestones are typically reached when a compound reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones are

typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Sales milestones are typically achieved when an approved pharmaceutical product exceed net sales as defined in each agreement.

For revenues from research, development and sales milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, such amounts are recognized entirely upon successful accomplishment of the milestones. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the period of performance. To date, Pieris has determined all milestones are substantive. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. Royalty payments are recognized in revenues based on the timing of royalty payments earned in accordance with the agreements, which typically is the period when the relevant sales occur, assuming all other revenue recognition criteria are met.

Government Grants

Government grants are recognized when there is reasonable assurance that all conditions will be complied with and the grant will be received. As the government grants generally represent subsidies for specified activities, they are recognized when earned as revenue from grants.

Funds received that are not related to research and development expenses that have already been incurred, such as the EUROCALIN grant, are recorded as deferred revenue until such time that the related expenses have been incurred by Pieris or by one of the other members of the EUROCALIN consortium. At the time eligible expenses are incurred, the applicable portion of deferred revenue according to the respective funding rates is recorded as revenue from grants.

Research and Development

Research and development costs are charged to expense as incurred. Research and development expenses consist of expenses incurred in performing research and development activities which are directly attributable to the creation of Pieris's Anticalin® class of biotherapeutics, including salaries and benefits; overhead expenses, including facilities expenses; materials and supplies; preclinical expenses; clinical trial and related clinical manufacturing expenses; depreciation of equipment; contract services; and other outside expenses. Legal fees incurred for patent application costs have been charged to expense and reported in research and development expenses.

Income Taxes

The Company applies ASC 740—*Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

From time to time the Company may receive tax credits in the form of cash in our Australian jurisdiction, irrespective of a tax liability. When a tax credit is due to us it is our policy to have that flow through operating expenses in the consolidated statements of operations, as this was where the original expense was recorded.

Stock-based Compensation

Pieris measures share-based payments in accordance with ASC Topic 718, *Stock Compensation*. Pieris records its stock-based compensation expense over the requisite service period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility and expected terms of the awards. For employee options, the fair value measurement date is generally on the date of grant and the related compensation expense is recognized on a straight-line basis over the requisite period of the awards, less expense for estimated forfeitures.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility, risk free interest rate and forfeitures of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the years ended December 31, 2015 and 2014 was $1.87 and $1.30, respectively based on the following assumptions:

	Years Ended December 31,	
	2015	2014
Risk free interest rate	1.47%-1.89%	1.77%
Expected term	5.0 – 6.1 years	5.6 – 5.8 years
Dividend yield	—	—
Expected volatility	72.65%-75.07%	74.66%

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities, and other factors due to the lack of historic information of the Company's common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the "simplified method" which is defined as the midpoint between the vesting date and the end of the contractual term. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary. Refer to Note 9 *Stock-Based Compensation,* for further information.

Pieris recorded stock-based compensation expense of $1.2 million and $0.6 million for the years ended December 31, 2015 and 2014, respectively.

Total stock-based compensation expense was recorded in operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows:

	Years Ended December 31,	
	2015	2014
Research and development	$ 379,066	$ 7,623
General and administrative	785,567	563,759
Total stock-based compensation	$1,164,633	$571,382

Warrants to Purchase Common Stock

Outstanding warrants are standalone instruments that are not puttable or mandatorily redeemable by the holder and are classified as equity awards. Pieris measures the fair value of the awards using the Black-Scholes option pricing model as of the measurement date using assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions for future events, expected volatility, expected life, yield, and risk-free interest rate. Issued warrants are recorded at fair value as a reduction in additional paid-in capital of the common stock issued. Refer to Note 11 *Warrants* for further information.

Contingencies

Accruals are recorded for loss contingencies when it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. Pieris evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously. Considering facts known at the time of the assessment, Pieris determines whether potential losses are considered reasonably possible or probable and whether they are estimable. Based upon this assessment, Pieris carries out an evaluation of disclosure requirements and considers possible accruals in the financial statements.

Segment Reporting

Operating segments are identified as components of an enterprise where separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and asses performance. Pieris operates as a single segment dedicated to the discovery and development of biotechnological applications and the Company's chief operating decision maker ("CODM") makes decisions based on the Company as a whole. The Company has determined that it´s CODM is its CEO.

Net Loss per Common Share

Basic net loss per share was determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per share was determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflect the dilutive effect, if any, of common stock options based on the treasury stock method.

For all financial statement periods presented the number of basic and diluted weighted average shares outstanding was the same because any increase in the number of shares of common stock equivalents for any period presented would be antidilutive based on the net loss for the period.

Shares to be issued upon the exercise of the outstanding options and warrants excluded from the loss per share calculation amounted to 2.6 million for the year ended December 31, 2015 because the awards were anti-dilutive. There were no shares to be issued upon the exercise of the outstanding options and warrants excluded from the loss per share calculation for the year ended December 31, 2014.

Accumulated Other Comprehensive Loss

Changes to accumulated other comprehensive income as of December 31, 2015 were as follows:

	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income
Balance—December 31, 2013	$ (956,273)	$ (956,273)
Current period other comprehensive loss	113,176	113,176
Balance—December 31, 2014	(843,097)	(843,097)
Current period other comprehensive loss	(429,477)	(429,477)
Balance—December 31, 2015	$(1,272,574)	$ (1,272,574)

Recent Accounting Pronouncements

Adopted Standards for current period

In November 2015, the FASB issued ASU No. 2015-17, *"Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes"*(ASU 2015-17). The amendments in ASU 2015-17 eliminates the current

requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will be required to classify all deferred tax assets and liabilities as noncurrent. This guidance is effective for fiscal years beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company does not believe this ASU will have a material impact on its financial statements. The Company has decided to early adopt ASU 2015-17 as of December 31, 2015 and is reflected in our income tax footnote (refer to Note 6—*Income taxes*). As a result of the early adoption of ASU 2015-17 the deferred tax assets reported in 2014 were netted. The overall impact to this adoption was not material to the overall financial statements.

Standards not yet adopted

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers," (ASU 2014-09) which provides guidance for revenue recognition. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for the Company beginning January 1, 2018, and at that time the Company may adopt the new standard under the full retrospective approach or the modified retrospective approach. Early adoption is not permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

In June 2015, the FASB issued ASU No. 2015-10, "Technical Corrections and Improvements" (ASU 2015-10). The amendments in ASU 2015-10 represent changes to clarify the FASB Accounting Standards Codification (the "Codification"), correct unintended application of guidance, or make minor improvements to the Codification that are not expected to have a significant effect on current accounting practice or create a significant administrative cost to most entities. In addition, some of the amendments are intended to make the Codification easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the Codification. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The Company does not believe this ASU will have an impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*". Under the amendments in ASU 2016-02 lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term for all leases (with the exception of short-term leases) at the commencement date. This guidance is effective for fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact the adoption of this standard will have on its financial statements and related disclosures.

Pieris has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

3. Acquisition

On December 17, 2014, Pieris, Pieris GmbH and the former shareholders of Pieris GmbH entered into an Acquisition Agreement (the "Acquisition Agreement"). Pursuant to the Acquisition Agreement, the former shareholders of Pieris GmbH contributed all of their equity interests in Pieris GmbH in exchange for 20,000,000 shares of the Company´s common stock, which resulted in Pieris GmbH becoming a wholly owned subsidiary of the Company (the "Acquisition").

On December 5, 2014, Pieris completed a 2.272727-for-1 forward split of its common stock in the form of a share dividend, with the result that 6,100,000 shares of common stock outstanding immediately prior to the stock

split became 13,863,647 shares of common stock outstanding immediately thereafter. Effective as of December 16, 2014, Pieris amended and restated its Articles of Incorporation to, among other things, change its name from Marika Inc. to "Pieris Pharmaceuticals, Inc." and increase its authorized capital stock from 75,000,000 shares of common stock, par value $0.001 per share, to 300,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share. On December 17, 2014, Pieris transferred its pre-Acquisition assets and liabilities to its former majority stockholder, Aleksandrs Sviks, in exchange for the surrender by him and cancellation of 11,363,635 shares of Pieris common stock.

In accordance with FASB, ASC Section 805 entitled "Business Combinations," Marika Inc. does not meet the definition of a business as it is a non-operating shell company. As a result, the Acquisition has been accounted for as a reverse-merger and recapitalization. Pieris GmbH is the acquirer for financial reporting purposes and Pieris is the acquired company. Consequently, the assets and liabilities and the operations reflected in the historical financial statements prior to the Acquisition are those of Pieris GmbH and are recorded at the historical cost basis of Pieris GmbH, and the consolidated financial statements after completion of the Acquisition include the assets and liabilities and results of operations of the combined Company. Share capital prior to the closing of the Acquisition has been retroactively adjusted to reflect the legal capital of Pieris.

4. Revenue

General

The Company has not generated revenue from product sales. The Company has generated revenue pursuant to (i) license and collaboration agreements, which include upfront payments for licenses or options to obtain licenses, payments for research and development services and milestone payments, and (ii) government grants.

	Years ended December 31,	
	2015	2014
License fees	$ —	$ 473,039
Research and development services	5,593	876,619
Milestone payments	2,538,698	3,184,988
Government grants	369,200	830,408
Other Revenues	18,440	—
Total Revenue	$2,931,931	$5,365,054

Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to $2.0 million, $0.5 million and $0.4 million, respectively, in the year ended December 31, 2015. Revenue from two collaboration partners and from one government grant exceeded 10% of total revenue, amounting to $3.0 million, $1.4 million and $0.7 million, respectively, in the year ended December 31, 2014.

Collaborations and Other Agreements

Daiichi Sankyo Co., Ltd.

In May 2011, Pieris granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company for targets selected by Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") pursuant to an agreement with Daiichi Sankyo. Under this agreement Pieris will use its proprietary Anticalin® scaffold technology to identify drug candidates against certain selected targets, with further development and commercialization performed by Daiichi Sankyo.

Daiichi Sankyo has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs and certain milestone payments as development

milestones are achieved. During the years ended December 31, 2015 and 2014, Pieris recorded revenue of $2.0 million and $3.0 million, respectively. The revenues recorded during the year ended December 31, 2015 were associated with achieving certain milestones within a research program. The revenues recorded during the year ended December 31, 2014 were associated with recognizing the final component of the upfront payment. Pieris provided various services in connection with the ongoing research programs as well as achieved development milestones during the years ended December 31, 2014.

The milestone payments in 2015 and 2014 are based on successful in vitro and in vivo studies and for the initiation on a toxicity study in non-human primates. The milestones could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, each of the milestone payments were recognized in their entirety as revenues during the respective years ended December 31, 2015 and 2014 in which they were received.

Pieris is entitled to receive potential milestone payments of $89.1 million, plus royalties on the commercial sales of any commercial products. The total milestones are categorized as follows: research milestones—$2.6 million; development milestones—$36.5 million; commercial milestones—$49.1 million; additional diagnostic milestones of $0.9 million.

Sanofi-Aventis and Sanofi-Pasteur

In September 2010, the Company entered into an agreement with Sanofi-Aventis and Sanofi Pasteur (“Sanofi”), under which the Company agreed to apply its proprietary Anticalin® technology to identify drug candidates against certain targets selected by Sanofi, with further development and commercialization performed by Sanofi. The agreement included the initial identification of two targets by Sanofi, with options to select up to four additional targets. For any targets selected by Sanofi, the Company granted an exclusive, worldwide license for the research, development and commercialization of drug candidates identified by the Company. In addition to the two initial targets selected by Sanofi, Sanofi exercised one of the four options and received a license. The remaining three options expired unexercised.

Sanofi has agreed to pay various upfront payments for certain research programs, payments for services provided by Pieris in conjunction with the research programs and certain milestone payments as development milestones are achieved. During the years ended December 31, 2015 and 2014, Pieris recorded revenue of $0.5 million and $1.4 million, respectively. The revenues recorded during the year ended December 31, 2015 were associated with achieving a development milestone within a research program during the period. The revenues recorded during the year ended December 31, 2014 were associated with recognizing the final component of the upfront payment as well as Pieris providing various services in connection with the ongoing research programs including achieving development milestones during the period.

The milestone payments in 2014 result from a positive review of a broad range of in vitro, in vivo and chemistry, manufacturing and control (“CMC”) data. The milestone payment in 2015 result from Sanofi´s decision to continue advancing the tetraspecific Anticalin-based program for infectious disease. The milestones could not be achieved solely upon the passage of time. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. Therefore, each of the milestone payments were recognized in their entirety as revenues during the respective years ended December 31, 2015 and 2014 in which they were received.

The Company is entitled to receive milestone payments up to $50.4 million, plus royalties on the sales of any commercial products. The total milestones are categorized as follows: research milestones—$1.9 million; development milestones—$28.9 million; commercial milestones—$19.6 million.

F.Hoffmann-La Roche Ltd and Hoffmann- La Roche Inc.

On December 8, 2015 the Company entered into a Research Collaboration and License Agreement with F.Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., collectively Roche, in cancer immune therapy for the research, development and commercialization of Anticalin-based drug candidates against a predefined, undisclosed target.

The parties will jointly pursue a preclinical research program with respect to the identification and generation of Anticalins that bind to a specific target for an expected period of 20 months, which may be extended under certain circumstances. Roche has the ability to continue exclusivity rights for up to an additional 5 years. During the research term of the agreement, Roche will fund the work to be performed by us pursuant to the research plan. Following the research program, Roche will be responsible for subsequent pre-clinical and clinical development of any product and will have worldwide commercialization rights.

Unless earlier terminated, the term of the agreement continues until no royalty or other payment obligations are or will become due under the agreement. The agreement may be terminated (i) by either party based on insolvency or breach by the other party and such insolvency proceeding is not dismissed or such breach is not cured within 90 days; or (ii) after 15 months from the effective date of the agreement, by Roche as a whole or on a product-by-product and/or country-by-country basis upon 90 days prior written notice before the first commercial sale of a product or upon 180 days prior written notice after the first commercial sale of a product. Roche may also, in its sole discretion, terminate the agreement upon a change of control of Pieris involving a company that develops or commercializes biopharmaceutical products.

Under the terms of the agreement Roche has agreed to pay an upfront payment of $6.5 million, which was received in January 2016, for the research program which will be recognized over the expected performance period, beginning on January 1, 2016. Roche also committed research funding, and the Company may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid-single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total consideration to us could surpass CHF 415 million ($415.7 million), excluding royalties.

Other Collaborations

The Company has entered into several other research and collaboration agreements for which the Company could achieve future milestone payments up to $14.0 million. For revenue recognition purposes, management determined these milestones to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangements as to whether the milestones would be achieved because of the numerous variables, such as the high rate of failure inherent in research and development activities and the uncertainty involved with obtaining regulatory approval. No milestones or other revenues related to these agreements were recognized during the years ended December 31, 2015 and 2014, respectively.

Government Grants

BioCluster m4

In 2011 Pieris applied for a government grant from the German Federal Ministry for Education and Research for the project “Spitzencluster m4, Cooperation personalized medicine: ‘Preclinical development of PRS-110 an Anticalin® targeted against c-Met as a monovalent antagonist in the field of oncology (PM18).’” The funding

rate amounts to 40% of the actual costs incurred, with an aggregate cap of $1.4 million for the approval period from February 1, 2012 to September 30, 2014. The amounts received are non-refundable, and the grant funds may only be claimed for costs incurred within the approval period.

The payments are received quarterly in arrears based on expenses already incurred. The Company recorded $8,654 and $0.1 million for the years ended December 31, 2015 and 2014, respectively, which was recorded as grant revenue.

Seventh Research Framework Program ("FP7")—Collaborative Project "EUROCALIN—European consortium for antiCALINs as next generation high-affinity protein therapeutics" ("EUROCALIN")

EUROCALIN is a program that started in August 2011 with the objective of developing and producing new high-affinity protein scaffolds for therapeutic use. The focus is on the development of non-immunoglobulin protein scaffolds as alternatives to antibodies and oligo-nucleotides. The grant involves a consortium of ten companies and universities in Europe and was initiated for a collaboration focused on attaining and completing initial clinical development of a novel Anticalin® therapeutic. The consortium is seeking to develop, manufacture and clinically test an Anticalin specific for hepcidin. The program is a small molecule enhancers ("SME") targeted project, which is funded by the European Union ("EU") in the amount of $7.3 million and also includes a respective funding rate of approximately 64% of the eligible costs occurred in connection with the research project. All payments received from the EU in connection with the grant are non-refundable. Under this grant agreement, Pieris is the coordinator. The EU has scheduled three tranches of payments. The first tranche (pre-financing) was received as of December 7, 2011 and the second tranche as of August 4, 2013. The third tranche was completed in November 2015 and is currently included in prepaid and other current assets on the consolidated balance sheet as the Company is awaiting final payment. Pieris, as the coordinator, receives all payments from the grant. The other members of the consortium are entitled to payments based on submission of invoices of eligible costs. Pieris pays the other members of the consortium based on the eligible costs. The Company owes the other member of the consortium an amount of $0.4 million and $0.3 million as of December 31, 2015 and 2014, respectively. Under this program the Company recognized $0.4 million and $0.7 million as revenue from grant during the years ended December 31, 2015 and 2014, respectively.

The following balance sheet items relate to the FP7 agreement:

	Years Ended December 31,	
	2015	2014
Other current assets (receivables from FP7 grant)	$ 980,936	$ 857,489
Cash (restricted cash)	$ 17,302	$ —
Accounts payable trade	$ 424,441	$ 325,864

5. Property and Equipment, net

Property and equipment are summarized as follows:

	Years Ended December 31,	
	2015	2014
Laboratory equipment	$ 3,701,517	$ 3,840,368
Office and computer equipment	443,562	343,835
Leasehold improvements	304,363	50,791
Property and equipment at cost	4,449,442	4,234,994
Accumulated depreciation	(2,286,671)	(2,182,773)
Property and equipment, net	$ 2,162,771	$ 2,052,221

Depreciation expense was $0.3 million and $0.4 million for the years ended December 31, 2015 and 2014, respectively. There were no other changes in accumulated depreciation other than foreign currency impact.

6. Income Taxes

(Loss) before income taxes consists of the following:

	Years Ended December 31,	
	2015	2014
Domestic	$ (7,563,300)	$(1,235,446)
Foreign	(6,291,475)	(8,614,536)
Loss before income taxes	$(13,854,775)	$(9,849,982)

The components of the provision (benefit) for income taxes are as follows:

	Years Ended December 31,	
	2015	2014
Current:		
Federal	$ —	$ —
State	—	—
Foreign	203,866	(18)
Total current	203,866	(18)
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision (benefit) for income taxes	$ 203,866	$ (18)

The reconciliation of the federal statutory rate to Pieris's effective tax rate is as follows:

	2015	2014
Federal income tax rate	34.0%	34.0%
Foreign rate differential	(2.1)%	(4.3)%
State tax, net of federal benefit	3.1	—
Permanent Items: Non-deductible expenses	(1.7)	(4.5)
Deferred adjustments	2.9	—
Loss of German NOL's	(66.0)	(74.2)
Withholding tax	(1.5)	—
Other	—	0.1
Change in valuation allowance	29.8	48.9
Effective income tax rate	(1.5)%	0.0%

The Company follows the provisions of FASB ASC 740, "Accounting for Uncertainty in Income Taxes—An Interpretation of FASB No. 109." FASB ASC 740 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with ASC 740-20. Tax positions must meet a "more-likely-than-not" recognition threshold at the effective date to be recognized upon the adoption of FASB ASC 740 and in subsequent periods. Pieris recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. No uncertain tax positions nor any interest and penalties related to uncertain tax positions were accrued at December 31, 2015 and December 31, 2014.

The Company operates in multiple countries. Accordingly, separate tax filings are required based on jurisdiction. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the U.S. or in its foreign jurisdictions to realize the full benefits of its U.S. deferred tax assets. As of December 31, 2015, we continue to maintain a full valuation allowance against all net deferred tax assets.

As of December 31, 2015, the Company has U.S. federal and state tax net operating loss carryforwards of approximately $6.0 million, which expire through 2035. Utilization of the tax net operating loss carryforwards may be limited in any year due to limitations in the Internal Revenue Code. As of December 31, 2015, the Company had Australia tax net operating loss carryforwards of approximately $0.3 million, which will not expire.

As of December 31, 2015, the Company had German corporate income tax and trade tax net operating loss carryforwards of approximately $5.9 million and $5.7 million respectively. Based on German tax law, the losses can be carried forward indefinitely. The operating loss carryforwards generated are subject to restrictions under German tax law. These regulations may limit the future use of operating loss carryforwards if there is a change in ownership. As a result of the ownership change Pieris GmbH experienced from the Acquisition and Private Placement in December 2014, the Company believes that it is more likely than not that future use of the net operating loss carryforwards that existed prior to the Acquisition may be limited significantly or forfeited entirely and as such the Company has written them off accordingly during the 2014 and 2015 period. The Company files federal income tax returns as well as returns in multiple foreign jurisdictions. Tax years ended December 31, 2013 or later remain subject to examination by the German tax authorities. Tax years ended December 31, 2014 and later remain subject to examination by the U.S. tax authorities.

The components of deferred tax assets and liabilities related to net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income taxes purposes were as follows:

	Years Ended December 31,	
	2015	2014
Deferred tax assets:		
Share based awards compensation	$ 692,906	$ —
Accrued expenses	4,201	—
Book accumulated depreciation net of tax	12,276	—
Net operating loss carryforwards	4,147,012	9,951,666
Bank loan	—	12,653
Accrued compensation	129,624	—
Other	10,149	1,129
Total deferred tax assets	4,996,168	9,965,448
Less: valuation allowance:	(4,996,168)	(9,916,553)
Net deferred tax asset	$ —	$ 48,895
Deferred tax liabilities:		
Accrued expenses	$ —	$ (8,811)
Prepaid expenses	—	(9,438)
Depreciation	—	(30,646)
Total deferred tax liabilities	—	(48,895)
Net deferred taxes	$ —	$ —

Tax field audit

On July 11, 2014, a tax field audit for the years 2010 to 2012 in accordance with §193 paragraph 1 AO under German law was announced by the tax office Freising. The tax field audit took place in July 2014. The results of the audit led to a reduction of the Company's net operating loss carryforwards on German corporate income tax by a total of $619,820 and a reduction of the Company´s net operating loss carryforwards on German corporate trade tax by a total of $644,795 for the years under the tax audit.

7. Debt

Convertible Stockholder Loans

In November 2012, the Company and several of its stockholders entered into an unsecured Convertible Stockholder Loan Agreement, which was subsequently amended in March 2014 (the "2012 Bridge Loan"). There were no outstanding principal or accrued interest balances under the 2012 Bridge Loan as of December 31, 2015 and 2014, respectively, due to the conversion to equity as discussed below. The 2012 Bridge Loan specified a maturity date of December 31, 2015 and an interest rate of 12% per year through December 31, 2013 and a rate of 18% per year subsequent to December 31, 2013.

On April 14, 2014, the Company entered into a second bridge loan agreement (the "2014 Bridge Loan" and together with the 2012 Bridge Loan, the "Bridge Loans") with certain of its stockholders pursuant to which the Company received a commitment for financing in the aggregate amount of €2,000,000 ($2,420,200). The 2014 Bridge Loan included two tranches of available financing: (i) Tranche A of €1,500,000 ($1,815,150) and (ii) Tranche B of €500,000 ($605,050). In June 2014, the Company borrowed 67% of Tranche A, or €1,000,000 ($1,210,100). There were no outstanding principal or accrued interest balances under the 2014 Bridge Loan as of December 31, 2015 and 2014, respectively due to the conversion to equity as discussed below. Loan amounts outstanding under the 2014 Bridge Loan accrued interest at a rate of 12% per year and had a maturity date of December 31, 2015, after which the loan amounts would accrue interest at a rate of 18% per year.

The Bridge Loans did not contain financial or non-financial covenants. During the fourth quarter of 2014, the investors in the Bridge Loans exercised their option to convert all of the outstanding principal and interest amounts under the Bridge Loan into shares. For more information refer to Note 8- *Stockholders´ Equity*. In 2014, $2.2 million were recognized for a beneficial conversion feature related to the Bridge Loans and was recorded as interest expense in the consolidated statement of operations.

In accordance with the Bridge Loans, the Company recognized interest expense of $326,429 for the year ended December 31, 2014. As the investors in the Bridge Loan exercised their option to convert all of the outstanding principal and interest amounts under the Bridge Loan into shares during the fourth quarter of 2014, no interest expense was recognized for the year ended December 31, 2015. No principal or interest payments were made for the Bridge Loans in 2015.

Four significant stockholders of the Company—Orbimed Private Investments III, LP, Gilde Europe Food & Agribusiness Fund B.V., The Global Life Science Ventures Funds (consists of The Global Life Science Venture Funds II GmbH & Co. KG, i.L. and The Global Life Science Venture Funds II Limited Partnership) and Coöperative AAC LS U.A. (Forbion B.V.)— are among the investors in Bridge Loans.

The Company recorded related-party interest expense concerning the Bridge Loan in the amounts set forth in the table below:

	Years ended December 31,	
	2015	2014
Orbimed Private Investments III, LP	$ —	$ 63,955
The Global Life Science Ventures Funds	—	57,709
Gilde Europe Food & Agribusiness Fund B.V.	—	54,158
Coöperative AAC LS U.A. (Forbion B.V.)	—	28,288
Total of related-party interest expense relating to the Convertible Bridge Loan	$ —	$ 204,110

Unsecured Bank Loan

In May 2003, the Company signed an unsecured loan agreement (the "Bank Loan") under a silent partnership agreement with Technologie-Beteiligungs-Gesellschaft ("TBG"), a minority interest stockholder. As of April 3, 2014, the Company and TBG, the subsidiary of KfW Bank, Frankfurt ("KfW"), signed a repayment agreement concerning the Company's repayment of its liabilities to TBG outstanding at December 31, 2013 in a total amount of €1.2 million ($1.34 million). The principal amount bore interest at a rate of 10.53%. On December 11, 2014, the Company and TBG entered into an accelerated repayment agreement in respect of the claims of TBG against the Company. Pursuant to terms of the accelerated repayment agreement and as stated on the 2014 consolidated balance sheet, conditioned upon closing of the Acquisition, the Company was obligated to pay €1,050,000 ($1.27 million), the outstanding amount under the repayment agreement, in two tranches as follows: €600,000 ($726,060) plus accrued interest on January 31, 2015 and €450,000 ($544,545) on March 31, 2015. The outstanding principal amount for the first and the second tranches net of capital gain tax withheld, was repaid in full in March 2015 and such next payment was €931,312 ($1,027,051). The capital gain tax withheld in the amount of €118,688 ($130,889) was paid on April 9, 2015 and no further amounts are payable in respect of TBG loan.

8. Stockholders' Equity

Common Stock

The Company has authorized 300,000,000 shares of common stock, par value $0.001 per share. As of December 31, 2015 and 2014 there were 39,833,023 and 29,279,522 shares of common stock issued and outstanding, respectively. As a result of the Acquisition, the equity structure of Pieris GmbH was retroactively adjusted using the exchange ratio established pursuant to the Acquisition Agreement to reflect the number of shares of the Company issued in the Acquisition.

Each share of the Company's common stock is entitled to one vote and all shares rank equally as to voting and other matters.

Dividends may be declared and paid on the common stock from funds legally available therefor, if, as and when determined by the Board of Directors.

Preferred Stock

The Company has authorized 10,000,000 shares of "blank check" preferred stock, par value $0.001 per share. There were no shares of preferred stock issued and outstanding during each of the years ended December 2015 and 2014. Shares of preferred stock may be issued in one or more series at such time or times and for such consideration as the Board of Directors may determine.

2014 Series C Financing

During the fourth quarter of 2014 and prior to the Acquisition, the Company completed a financing round and issued the equivalent of 10,671,037 shares of common stock. This financing included an issuance of the equivalent of 5,662,167 shares of common stock for aggregate cash proceeds of $7.4 million. Additionally, outstanding principal and interest related to the Bridge Loans of $4.4 million was converted into 5,008,870 shares of common stock.

Acquisition

Immediately following the closing of the Acquisition in December 2014, the Company´s outstanding shares of common stock (on a fully diluted basis) were as follows:

- former holders of Pieris AG's capital stock held an aggregate of 20,000,000 shares of the Company´s common stock;
- holders of Marika Inc.'s common stock prior to the closing of the Acquisition hold an aggregate of 2,500,012 shares of the Company's common stock;
- 3,200,000 shares of common stock were reserved for issuance under the 2014 Employee, Director and Consultant Equity Incentive Plan of Pieris Pharmaceuticals, Inc. (the "Pieris Plan") As of December 31, 2014, options to purchase 2,519,500 shares of the Company´s common stock have been issued under the Pieris Plan to executive officers, directors, employees and consultants. As a result of such grants, 680,500 shares of the Company´s common stock are available for future issuance under the Pieris Plan.

Private Placement

On December 17, 2014, subsequent to the Acquisition, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain accredited investors (the "Investors") providing for the issuance and sale to such Investors of an aggregate of 6,779,510 shares of the Company´s common stock in a private placement offering conducted through a series of closings occurring in December 2014, at a purchase price per share of $2.00 and for aggregate gross proceeds to the Company of $13.6 million (the "Private Placement"). After deducting for placement agent and other fees, the aggregate net proceeds from the Private Placement were $12.0 million. Northland Securities, Inc. and Katalyst Securities, LLC served as co-exclusive placement agents (the "Placement Agents") for the Private Placement.

The Securities Purchase Agreement also contained certain anti-dilution provisions. Those anti-dilution provisions provided that if the Company issued and sold equity securities or equity-linked or related securities at a purchase price per share of lower than $2.00 within the 180-day period following December 17, 2014, each Investor in the Private Placement would be entitled to receive such number of additional shares of the Company´s common stock as they would have received had such lower purchase price per share been applicable in the Private Placement. The 180-day period has passed as of December 31, 2015 and no anti-dilution provisions were triggered.

At the closings of the Private Placement the Company issued to the Placement Agents and their designees, warrants (the Placement Warrants) to acquire up to 542,360 shares of its common stock at an exercise price of $2.00 per share. Each of the Placement Warrants is exercisable at any time at the option of the holder until the five-year anniversary of its date of issuance. For more information refer to Note 11 *Warrants*.

Public Offering

On July 6, 2015 the Company closed a public offering of an aggregate of 9,090,909 shares of the Company´s common stock at a purchase price of $2.75 per share. All shares of common stock were offered by the Company. On July 24, 2015 the underwriters exercised their over-allotment option to purchase 1,211,827 additional shares of the Company's common stock at the public offering price of $2.75, the sale of which closed on July 28, 2015.

Gross proceeds raised by the Company in the offering, including the exercise of the over-allotment option, were $28.3 million and net of equity issuance costs are $25.8 million. The Company intends to use the net proceeds from the offering to fund research and development, including preclinical and clinical research and development of its drug candidates, working capital and general corporate purposes.

As result of the Acquisition, the Private Placement, the Public Offering and the Consulting Shares (for more information on the Consulting Shares refer to Note 10 *Consulting Shares*) the Company has 39,833,023 shares of common stock issued and outstanding at December 31, 2015.

9. Stock-Based Compensation

In December 2014, the Company adopted the 2014 Employee, Director and Consultant Equity Incentive Plan, (the "Plan") which provides for the grant of stock options to certain designated employees of the Company, non-employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors. At December 31, 2015, the number of common shares reserved for issuance under the 2014 plan was 3,200,000. In addition the Plan provides for an "evergreen" provision whereby the number of shares of the Company´s common stock reserved for issuance under the Plan shall be automatically increased on January 1 of each of year commencing in fiscal 2016 by the lesser of (i) 1,000,000 shares, (ii) 4% of the number of shares of the Company´s common stock outstanding on such date, and (iii) such other amount determined by the Compensation committee of the Board of Directors. Vesting periods are determined by our Board of Directors; options primarily vest over a three or four year period. As of December 31, 2015, there were 487,671 shares available for future grant under the Plan.

The Company's stock options have a maximum term of ten years from the date of grant. Stock options granted under the Plan may be either incentive stock options ("ISOs"), or nonqualified stock options. The exercise price of stock options granted under the Plan must be at least equal to the fair market value of the common stock on the date of grant. The Company's general policy is to issue common shares upon the exercise of stock options.

Cash received from option exercises was $10,000 during the year ending December 31, 2015. There were no option exercises in the year ended December 31, 2014.

Pieris granted 755,329 and 2,519,500 stock options during the years ended December 31, 2015 and 2014, respectively. Of these stock options granted in the 2015 period, an option for 450,000 shares was granted to a newly-hired executive officer subject to certain restrictions on exercise that require the Company´s shareholders to approve an increase in the number of shares authorized under the Plan; if such shareholder approval is not obtained by September 30, 2016, the option will be cancelled and of no further force and affect. This option, therefore, does not have impact on the remaining shares available for future grants currently authorized under the Plan and no compensation expense was recorded in 2015.

The Company granted an option to purchase 500,000 shares outside of the Plan to a newly-hired executive officer that was an inducement option, material to the executive officer entering into employment with the Company during the 2015 period. The compensation expense with this inducement option was $0.1 million and is included in research and development expense for the year ended December 31, 2015.

A summary of the status of the Company's stock option plans as of December 31, 2015 and changes during the year then ended is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2014	2,519,500	$ 2.00	9.96 years	$ —
Granted	305,329	2.47		
Exercised	(5,000)	2.00		1
Forfeited	(112,500)	2.00		
Outstanding, December 31, 2015	2,707,329	$ 2.05	9.17 years	$ 741
Vested or expected to vest	2,707,329	$ 2.05	9.17 years	$ 741
Exercisable, December 31, 2015	1,209,601	$ 2.06	9.17 years	$ 328

Excluded from the table above is the option to purchase 500,000 shares outside of the Plan granted to a newly-hired executive officer. The weighted-average exercise price of these options amounts to $3.36 with a remaining contractual life of 9.63 years.

10. Consulting Shares

Del Mar Consulting Group & Alex Partners

On March 6, 2015, the Company entered into an independent consulting agreement (the "Consulting Agreement") with the Del Mar Consulting Group, Inc. and Alex Partners, LLC (the "Consultants"), pursuant to which the Company issued 150,000 restricted shares of its common stock (par value $0.01 per share) to the Consultants (the "Consulting Shares"). The Company agreed to retain the Consultants to provide investor relations consulting to the Company for a period commencing on March 6, 2015 (the "Commencement Date") and ending thirteen months after the Commencement Date (such period, the "Term"). The shares issued in connection with the Consulting Agreement were deemed to be exempt from registration in reliance upon Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving any public offering.

The terms of the Consulting Agreement state that Pieris has the right to terminate this agreement at any time during the Term of the Consulting Agreement, upon providing Consultants ten days' written notice of the Company's intention to terminate or immediately upon notice in the event of a breach of this agreement by either consultant. If the Company had elected to terminate this agreement for any reason within one hundred eighty days (180) following the effective date each Consultant would have been required to promptly surrender to the Company forty percent (40%) of the number of Consulting Shares issued to it.

The Company uses the Black-Scholes model and estimated the fair value of the 90,000 non-cancellable Consulting Shares to be $0.3 million based on the closing price per share of $3.16 as quoted on the OTCQB tier of the OTC Markets Group Inc., or the OTCQB, on the grant date, March 6, 2015. The remaining 60,000 shares were then marked to market based on the Black-Scholes model at each reporting period with the expense being recorded in the consolidated statement of operations as general and administrative expenses.

On September 2, 2015, the remainder of the Consulting Shares vested and the remaining expense was recorded based on the fair value of the shares on that date. The Company recorded expense in an amount of $0.4 million for the non-cancellable and cancellable Consulting Shares for the year ended December 31, 2015.

Aquilo Partners

On September 4, 2015 the Company entered into a Letter Agreement (the "Letter Agreement") with Aquilo Partners, L.P. ("Aquilo Partners"). Aquilo Partners has been engaged by the Company as an advisor.

Upon execution of the Letter Agreement, the Company has recorded a retainer fee of $0.1 million. In addition to the cash retainer fee, the Company issued 27,272 shares of the Company's common stock equal in value to $0.1 million based on the closing price of $2.75 per share of the Company's common stock on September 4, 2015, the date of the Letter Agreement. The compensation for Aquilo Partners has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015.

Trout Capital LLC

On November 20, 2015 the Company entered into an Agreement with Trout Capital LLC for advisory services. Upon execution of this agreement, Trout Capital was entitled to receive a one-time transaction fee. The Company issued 68,493 shares of the Company's common stock equal in value to $0.2 million based on the closing price of $2.19 per share of the Company's common stock on November 20, 2015, the date of the agreement. The compensation for Trout Capital LLC has been recorded in the consolidated statements of operations as general and administrative expenses for the year ended December 31, 2015.

11. Warrants

In connection with the Private Placement, the Company issued the Placement Warrants to acquire a combined up to 542,360 shares of its common stock at an exercise price of two dollars per share ($2.00) to the Placement Agents and their designees. The Placement Warrants are exercisable at any time at the option of the holder until the five year anniversary of its date of issuance. The number of shares of common stock issuable upon the exercise of each Placement Warrant is adjustable in the event of certain stock dividends, stock splits, combinations of shares and similar transactions. Upon exercise, the aggregate exercise price of the warrants issued are payable by the holders in cash.

The Company estimated the fair value of the Placement Warrants as of the grant date to be $0.7 million and recognized the full amount in general and administrative expense for the year ended December 31, 2014. There was no expense associated with the Placement Warrants for the year ended December 31, 2015.

Pursuant to ASC 815-15 and ASC 815-40, the fair value of the Placement Warrants was recorded as equity awards on the grant dates. The Placement Warrants were valued at their grant dates using the Black-Scholes pricing model and the following weighted average assumptions:

	December 31, 2014
Dividend yield	0.00%
Expected volatility	74.66%
Weighted average risk-free interest rate	1.61%
Expected term (years)	5.00

12. Accrued Expenses and Other Liabilities

Accrued expenses consist of the following:

	Years Ended December 31,	
	2015	2014
Accrued expenses and other current liabilities		
Accrued payroll and benefits	$ 704,597	$ 416,896
Accrued audit and tax fees	179,223	—
Accrued professional fees	194,790	404,461
Accrued R&D fees	466,076	—
Accrued other	194,694	165,263
Total amount of accrued expenses and other current liabilities	1,739,380	986,620
Accrued expenses and other non-current liabilities		
Reserve for litigation TUM	—	327,937
Accrued other, non-current	23,852	6,051
Total amount of accrued expenses and other non-current liabilities	23,852	333,988
Total amount of accrued expenses and other liabilities	$1,763,232	$1,320,608

13. Related-Party Transactions

Research and License Agreement with Technische Universität München

On July 4, 2003, the Company entered into the TUM License Agreement, which was subsequently renewed and, on July 26, 2007, superseded and replaced. The agreement established a joint research effort led by Prof. Arne Skerra, Chair of Biological Chemistry of TUM, to optimize Anticalin® technologies for use in therapeutic, prophylactic and diagnostic applications and as research reagents, and to gain fundamental insights in lipocalin scaffolds. Prof. Dr. Skerra was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the consolidated financial statements in this report. The Company provided certain funding for TUM research efforts performed under the agreement.

As a result of research efforts to date under the agreement, the Company holds a worldwide exclusive license under its license agreement with TUM to multiple patents and patent applications, including an exclusive license to an issued U.S. patent, which patent will expire in 2027 (subject to a possible term adjustment period). The Company also holds an exclusive license to an issued U.S. patent No. 8,420,051, which patent is expected to expire in 2029. The Company bears the costs of filing, prosecution and maintenance of patents assigned or licensed to the Company under the agreement.

As consideration for the assigned patents and licenses above, the Company was required to pay certain development milestones to TUM. The Company is also obliged to pay low-single-digit royalties, including annual minimum royalties, on sales of such products incorporating patented technologies. If the Company grants licenses or sublicenses to those patents to third parties, the Company will be obliged to pay a percentage of the resulting revenue to TUM. The Company's payment obligations are reduced by the Company´s proportionate contribution to a joint invention. Payment obligations terminate on expiration or annulment of the last patent covered by the agreement. The Company can terminate the licenses to any or all licensed patents upon specified advance notice to TUM. TUM may terminate the license provisions of the agreement only for cause. Termination of the agreement does not terminate the rights in patents assigned to the Company. The Company has incurred expenses related to TUM in connection with the transfer of licenses and protective rights of $41,791 during the nine month period ended September 30, 2015. Effective as of the fourth quarter of 2015, Pieris no longer deems TUM a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. The Company has incurred expenses related to TUM as a related party of $0.1 million for the year ended December 31, 2014.

The part of the agreement requiring the Company to make payments for research conducted by TUM expired in February 2013 with no further obligations by the Company.

EUROCALIN/FP7 Government Grant

TUM is a member of the EUROCALIN consortium and thus is entitled to receive payments under the grant agreement for research activities. Research activities are carried out by Prof. Dr. Skerra, who was a member of the Company's supervisory board when the parties entered into such agreement and during the period covered by the financial statements in this report. As Pieris AG was transformed to Pieris GmbH the change in legal entity removed the requirement of having a supervisory board; accordingly Prof. Dr. Skerra no longer holds a seat on the supervisory board. The government grant agreement with FP7 is further discussed in Note 4—Revenue.

Receivables from Issuance of Shares

In connection with the issuance of nominal stock, payments of the share premium into additional paid in capital were deferred. Amounts were deferred for Claus Schalper and Prof. Dr. Skerra among others. During 2008 through July 31, 2013, Mr. Schalper was the Chief Financial Officer of Pieris GmbH, and since August 1, 2013, has served as a consultant to Pieris GmbH. During 2001 and through October 10, 2014, Prof. Dr. Skerra was the deputy chairman of Pieris GmbH supervisory board. In connection with the consummation of the Acquisition, the Company waived all deferred payment claims against the aforementioned stockholders.

Consulting Contract between Prof. Dr. Arne Skerra and the Company

In 2001, the Company entered into a Consulting Agreement with Prof. Dr. Skerra, pursuant to which Prof. Dr. Skerra provides advice regarding the use of new proteins, in particular Anticalin® proteins and antibodies, for the purpose of research and development. The Consulting Agreement has an unlimited term but can be terminated by the Company upon three months' notice with effect from the end of a month and by Prof. Dr. Skerra upon one year's notice with effect from the end of a year. Under the Consulting Agreement, the Company incurred and paid to Prof. Dr. Skerra consulting fees of $16,717 during the nine months ended September 30, 2015. As of the fourth quarter of 2015 Pieris no longer deems Prof. Dr. Skerra a related party due to Prof. Dr. Skerra no longer having a supervisory board position in Pieris GmbH or other direct relationship with the Company after the Acquisition. The Company incurred and paid to Prof. Dr. Skerra consulting fees of $26,593 for the year ended December 31, 2014.

Convertible Stockholder Loan

Four significant stockholders of the Company—Orbimed Private Investments III, LP, Gilde Europe Food & Agribusiness Fund B.V., The Global Life Science Ventures Funds (consists of The Global Life Science Venture Funds II GmbH & Co. KG, i-L. and The Global Life Science Venture Funds II Limited Partnership) and Coöperative AAC LS U.A. (Forbion B.V.)—participated as investors in the Bridge Loans as related parties. The Bridge Loans are further discussed in Note 7 *Debt.*

14. Commitments and Contingencies

Licensing Commitments

The Company has license agreements with two parties under which the Company is obliged to pay annual license fees. One agreement is between IBA GmbH and the Company which requires annual license payments of $32,718 and relates to licenses for Strep-tag technology that represent tool technologies and which are used for research purposes only. The agreement expires in 2024.

Another license agreement exists between TUM and the Company (see Note 13 *Related-Party Transactions*). Under this agreement, the Company is obliged to pay a minimum annual license fee of $0.1 million to TUM. The agreement expires in 2027.

The table below shows the minimum annual license fee commitments under the two agreements as of December 31, 2015:

	License payments
2016	$ 87,248
2017	87,248
2018	87,248
2019	87,248
2020	87,248
Thereafter	512,582
Total minimum license payments	$948,822

Leases

The Company leases office and laboratory space in Freising, Germany. The lease has a defined termination date which is the end of a notification period of eight months at the end of each quarter. On August 27, 2015 the Company entered into an Agreement of Sublease (the "Sublease Agreement") with Berenberg Capital Markets LLC (the "Sublandlord"). Under the Sublease Agreement, the Sublandlord will sublease to the Company approximately 3,950 square feet in Boston, MA. The term of the lease shall expire on February 27, 2022. The Sublease Agreement provides for free rent for the first two months in addition to scheduled rent increases that are not dependent on future events.

The Company records rent expense on a straight-line basis over the lease term period. For the year ended December 31, 2015, the Company has recognized rent expense in an amount of $18,399 under the Sublease Agreement. Rent expense under the Company's operating lease for its Freising, Germany based facility was $0.4 million and $0.3 million for the years ended December 31, 2015 and 2014, respectively.

The Company's contractual commitments of the non-cancellable portion under theses operating leases as of December 31, 2015 are as follows:

	Total
2016	$ 318,186
2017	188,009
2018	191,959
2019	195,909
2020	199,859
Thereafter	238,371
Total minimum lease payments	$1,332,293

TUM Arbitration

Under the TUM License Agreement, the Company is required to make payments to TUM based on the Company's revenues generated from entering into sub-licensing agreements with any third party with respect to University Inventions and/or Joint Inventions (each as defined in the TUM License Agreement). These revenues include upfront license payments as well as milestone payments received by the Company from third parties. The Company has signed six such sub-licensing agreements between 2004 and 2012 (the period under dispute), under which it has recorded revenues. The Company acknowledges an obligation to TUM; however, the parties disagree regarding the amount due.

On March 20, 2014, the Company instituted arbitration proceedings, or the TUM Arbitration, against Technische Universität München, or Munich Technical University and hereafter TUM, to address issues regarding the calculation of payments due from the Company to TUM under the TUM License Agreement. Pursuant to the terms of the TUM License Agreement, the arbitration is proceeding in Munich, Germany and governed by German law, in accordance with the arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit (the "DIS").

On July 4, 2003, or the Effective Date, the Company and TUM entered into the TUM License Agreement, as superseded and replaced on July 26, 2007, under which TUM has exclusively licensed, or in some cases assigned, to the Company certain intellectual property and know-how that has become part of the Anticalin® proprietary technologies. In return, the Company agreed to pay to TUM certain undisclosed annual license fees, milestones and royalties for its own proprietary drug development and sales, as well as an undisclosed variable fee as a function of out-licensing revenues, or the Out-License Fee, where such Out-License Fees are creditable against annual license payments to TUM.

As required by the TUM License Agreement, the Company provided to TUM its calculation of the Out-License Fee owed by the Company to TUM for the period beginning on the Effective Date and ending on December 31, 2012, the Dispute Period, in the amount of $0.3 million excluding value-added tax. TUM has asserted that, under the TUM License Agreement, the Out-License Fee due to TUM for the Dispute Period amounts to $3.4 million excluding value-added tax in the aggregate and has threatened to terminate the TUM License Agreement if the Out-License Fee is not paid. The Company believes that if TUM sought to terminate the license agreement for cause as a result of this dispute, it would potentially face wrongful termination claims for substantial damages if the arbitral tribunal in the TUM Arbitration sides with the Company in its final decision regarding the proper amount of the Out-License Fee, but the Company can provide no assurance regarding the timing, nature or consequences of such decision. The Company commenced the TUM Arbitration to request that the arbitration tribunal hold that the Company's calculation of the payments owed to TUM is accurate and shall govern all current and future payments due in respect of the Out-License Fee under the TUM License Agreement. On December 1, 2014, TUM filed its statement of defense maintaining its earlier calculation of the Out License Fee. On December 23, 2014, TUM filed a counterclaim in the amount of €2.5 million ($2.8 million) to suspend the statute of limitations on its claim. The Company has reserved a liability on its balance sheet in respect of such payment in the amount of €0.3 million ($0.3 million). An adverse ruling in the TUM Arbitration could have a material adverse effect on the Company's results of operations and financial condition.

On November 19, 2015, the Company received notification from the DIS of the arbitration tribunal's award. In its award, as corrected on January 25, 2016, the tribunal dismissed the Company's request for declaratory judgment and granted TUM's counterclaim in an amount of €0.9 million ($0.9 million) of which, $0.6 million is recorded as research and development expense in the consolidated statement of operations for the 2015 period due to a previous liability of $0.3 million recorded for the arbitration settlement as of December 31, 2014. Interest expense of $0.2 million was also included in the settlement and is recorded in the consolidated statement of operations as interest expense, net. The tribunal dismissed the remainder of TUM's counterclaim.

The Tribunal also ruled that TUM must reimburse the Company in the amount of €0.1 million ($0.1 million) for legal fees incurred and dismissed TUM's claim for reimbursement of its costs. The Company has decided not to challenge the award and paid the amount as calculated by the arbitration panel. The deadline for filing a motion to set aside the award expired on February 15, 2016.

EXHIBIT 4.2

ZQ|CERT#|COY|CLS|RGSTRY|ACCT#|TRANSTYPE|RUN#|TRANS#

COMMON STOCK

PAR VALUE $0.001

COMMON STOCK

THIS CERTIFICATE IS TRANSFERABLE IN CANTON, MA; JERSEY CITY, NJ AND COLLEGE STATION, TX

Certificate Number
ZQ00000000

Shares

PIERIS PHARMACEUTICALS, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF NEVADA

THIS CERTIFIES THAT

MR. SAMPLE & MRS. SAMPLE &
MR. SAMPLE & MRS. SAMPLE

CUSIP 720795 10 3

SEE REVERSE FOR CERTAIN DEFINITIONS

is the owner of

***ZERO HUNDRED THOUSAND
ZERO HUNDRED AND ZERO***

Shares of **Pieris Pharmaceuticals, Inc.** Common Stock

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this Certificate properly endorsed. This Certificate is not valid until countersigned by the Transfer Agent and registered by the Registrar.

Witness the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

President

Treasurer

PIERIS PHARMACEUTICALS, INC. CORPORATE SEAL NEVADA

DATED DD-MMM-YYYY

COUNTERSIGNED AND REGISTERED:
COMPUTERSHARE TRUST COMPANY, N.A.
TRANSFER AGENT AND REGISTRAR,

By _____
AUTHORIZED SIGNATURE

SECURITY INSTRUCTIONS ON REVERSE

1234567

PO BOX 43004, Providence, RI 02940-3004

MR A SAMPLE
DESIGNATION (IF ANY)
ADD 1
ADD 2
ADD 3
ADD 4

CUSIP	XXXXXX XX X
Holder ID	XXXXXXXXXX
Insurance Value	1,000,000.00
Number of Shares	123456
DTC	12345678 12345678901234 5

Certificate Numbers	Num'No.	Denom.	Total
12345678901234567890	1	1	1
12345678901234567890	2	2	2
12345678901234567890	3	3	3
12345678901234567890	4	4	4
12345678901234567890	5	5	5
12345678901234567890	6	6	6
Total Transaction			7

PIERIS PHARMACEUTICALS, INC.

THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHAREHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE ARTICLES OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE AUTHORITY OF THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR FUTURE SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE OWNER OF A LOST OR DESTROYED STOCK CERTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT	-.....(Cust).....Custodian.....(Minor).....
TEN ENT	- as tenants by the entireties		under Uniform Gifts to Minors Act.....(State).....
JT TEN	- as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT	-.....(Cust).....Custodian (until age .....) .....(Minor).....under Uniform Transfers to Minors Act .....(State).....

Additional abbreviations may also be used though not in the above list.

NOTICE: Signature must be guaranteed by a firm which is a member of a registered national stock exchange, or by a bank (other than a savings bank), or a trust company. The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations.

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

For value received, _____ hereby sell, assign and transfer unto

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the capital stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated: _____ 20____

Signature: _____

Signature: _____

Notice: The signature to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration or enlargement, or any change whatever.

Signature(s) Guaranteed: Medallion Guarantee Stamp

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15.

EXHIBIT 10.11

CONFIDENTIAL TREATMENT REQUESTED

Research Collaboration and License Agreement

This Agreement is entered into with effect as of the Effective Date (as defined below)

by and between

F. Hoffmann-La Roche Ltd

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("**Roche Basel**")

and

Hoffmann-La Roche Inc.

with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. ("**Roche US**"; Roche Basel and Roche US together referred to as "**Roche**")

on the one hand

and

Pieris Pharmaceuticals GmbH

with an office and place of business at Lise-Meitner-Str. 30, 83534 Freising, Germany **("Pieris Freising**")

and

Pieris Pharmaceuticals, Inc.

with an office and place of business at 255 State Street, 9th Floor, Boston, MA 02109, USA **("Pieris US**"; Pieris Freising and Pieris US together referred to as "**Pieris**")

on the other hand.

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

Table of Contents

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

WHEREAS, Pieris has access to a proprietary Anticalin® (lipocalin derived) discovery and manufacturing platform and possesses proprietary technology and intellectual property rights relating thereto; and

WHEREAS, Roche has access to the [***] and [***] target protein and other tools and to [***] for [***] as well as expertise in the research, development, manufacture and commercialization of pharmaceutical and diagnostic products, in particular in the field of cancer immunotherapy; and

WHEREAS, the Parties wish to combine their respective expertise to develop binders that [***]or [***] to [***] using Pieris Technology and Roche's [***] for application in particular in cancer, and the Parties will collaborate from the beginning of lead identification through a mutually agreeable preclinical research stage set forth in the Research Plan.

WHEREAS, Roche wishes to develop for commercialization such binders and explore their potential applications in various indications; and

WHEREAS, Pieris is willing to grant to Roche rights to use certain of its intellectual property rights to make, use, offer for sale, sell and import and export such binders (including Products containing such binders) in the Territory for use in the Field (as such terms are respectively defined below), as contemplated herein; and

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Affiliate

The term "Affiliate" shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of "Affiliate," the term "control" shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, Chugai Pharmaceutical Co., Ltd, a Japanese corporation ("**Chugai**") and Foundation Medicine, Inc., an American corporation ("**Foundation**") and their subsidiaries, shall not be deemed an Affiliate of Roche unless Roche provides written notice to Pieris of its desire to include Chugai and/or Foundation as an Affiliate of Roche.

1.2 Agreement

The term "Agreement" shall mean this document including any and all appendices and amendments to it as may be added and/or amended from time to time in accordance with the provisions of this Agreement.

1.3 Agreement Term

The term "Agreement Term" shall mean the period of time commencing on the Effective Date and, unless this Agreement is terminated sooner as provided in Article 19, expiring on the date when no royalty or other payment obligations under this Agreement are or will become due.

1.4 Anticalin®

The term "Anticalin®" shall mean, whether in nucleic acid or protein form, (i) any lipocalin mutein isolated from the Anticalin Libraries, or (ii) any lipocalin mutein that, in each case, has been derived (either physically, intellectually or by reverse engineering, in one (1) or more steps) from any lipocalin mutein referred to in Section (i) of this definition. For the sake of this Section, mutein shall mean a protein arising as a result of a mutation or a recombinant DNA procedure.

1.5 Anticalin Affinity Maturation

The term "Anticalin Affinity Maturation" shall mean the process of engineering for an Anticalin to enhance its developability profile, such as increasing binding activities and specificity by introducing, e.g., one or more amino acid mutations.

1.6 Anticalin Expression

The term "Anticalin Expression" shall mean heterologous expression of an Anticalin in E. coli or other hosts as may be mutually agreed between the Parties.

1.7 Anticalin Libraries

The term "Anticalin Libraries" shall mean any phage display library based on (i) the human [***] lipocalin (Uniprot [***]), (ii) the human [***] lipocalin (Uniprot [***]), or (iii) [***], if applicable. For clarity, as of the Effective Date, Pieris [***] referred to in Section (iii) of this definition and this Section (iii) only becomes relevant if and when Pieris [***] or [***] such [***] during the Agreement Term. For further clarity, notwithstanding anything to the contrary in this Agreement, Pieris has no obligation to [***] or [***] such [***] during the Term.

1.8 Anticalin Selection

The term "Anticalin Selection" shall mean the process of screening an Anticalin Library with a defined target through the process of phage display, within a solution, and physically separating the target, containing binding Anticalins, from the solution containing non-binding Anticalins.

1.9 Applicable Law

The term "Applicable Law" shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including without limitation, any Regulatory Authority and the United States Securities and Exchange Commission ("SEC")) and is in force as of the Effective Date or come into force during the Agreement Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement.

1.10 Binder

The term "Binder" shall mean an Anticalin® discovered under the Research Plan that [***] or [***] the Target.

1.11 Biosimilar Product

The term "Biosimilar Product" shall mean a product that is not produced, licensed or owned by the Roche Group and is, according to the relevant Regulatory Authority for the given country or jurisdiction, highly similar with respect to a given Product, notwithstanding minor differences in clinically inactive components, and with no clinically meaningful differences between the Biosimilar Product and the given Product in terms of the safety, purity and potency of the product.

For countries or jurisdictions where no explicit biosimilar regulations exist, Biosimilar Product includes products which (i) have been deemed to be a Biosimilar Product by a Regulatory Authority in another country or jurisdiction or (ii) have the identical amino acid sequence.

1.12 Calendar Quarter

The term "Calendar Quarter" shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31.

1.13 Calendar Year

The term "Calendar Year" shall mean the period of time beginning on January 1 and ending December 31, except for the first year which shall begin on the Effective Date and end on December 31.

1.14 Change of Control

The term "Change of Control" shall mean, with respect to a Party: (a) the acquisition by any Third Party of beneficial ownership of fifty percent (50%) or more of the then outstanding common shares or voting power of such Party, other than acquisitions by employee benefit plans sponsored or maintained by such Party; (b) the consummation of a business combination involving such Party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (50%) of the then outstanding common shares or voting power of the entity resulting from such business combination; or (c) the sale of all or substantially all of such Party's assets or business relating to the subject matter of the Agreement.

1.15 Change of Control Group

The term "Change of Control Group" shall mean with respect to a Party, the person or entity, or group of persons or entities, that is the acquirer of, or a successor to, a Party in connection with a Change of Control, together with affiliates of such persons or entities that are not Affiliates of such Party immediately prior to the completion of such Change of Control of such Party.

1.16 Clinical Study

The term "Clinical Study" shall mean a Phase I Study, Phase II Study, Phase III Study, as applicable.

1.17 Combination Product

The term "Combination Product" shall mean

a) a single pharmaceutical formulation containing as its active ingredients either (i) a [***] or (ii) a [***], in each case together with one or more other therapeutically or prophylactically active ingredients targeting an antigen other than the Target. For clarity, Combination Product in this Subsection a) also includes a [***] comprised of a [***] or [***] or [***] to [***] an[***],

b) a combination therapy comprised of a [***] or [***] alone (or combined as described in a) above) and one or more other therapeutically or prophylactically active products, priced and sold in a single package containing such multiple products or packaged separately but sold together for a single price, or

c) a combination therapy comprised of a [***] alone (or combined as described in a) above) and a Companion Diagnostic, priced and sold in a single package containing such multiple products or packaged separately but sold together for a single price,

in each case, including all dosage forms, formulations, presentations, line extensions, and package configurations.

1.18 Commercially Reasonable Efforts

The term "Commercially Reasonable Efforts" shall mean such level of efforts required to carry out such obligation in a sustained manner consistent with the efforts Roche or Pieris, as applicable, devotes at the same stage of development or commercialization, as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life taking into account the existence of other competitive products in the market place or under development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors. It is understood that such product potential may change from time to time based upon changing scientific, business and marketing and return on investment considerations.

However, Roche (and its Affiliates) does not always seek to market its own products in every country or seek to obtain regulatory approval in every country or for every potential indication. As a result, the exercise of diligence by Roche is to be determined by judging Roche's commercially reasonable efforts, taken as a whole.

1.19 Companion Diagnostic

The term "Companion Diagnostic" shall mean any product that is used for predicting and/or monitoring the response of a human being to treatment with a Product (e.g. device, compound, kit, biomarker or service that contains a component that is used to detect or quantify the presence or amount of an analyte in body or tissue that affects the pathogens of the disease).

1.20 Composition of Matter Claim

The term "Composition of Matter Claim" shall mean, for a given Product in a given country of the Territory, a Valid Claim of a Patent Right that Covers the active ingredient of a Product as a composition of matter.

1.21 Compulsory Sublicense

The term "Compulsory Sublicense" shall mean a license or sublicense granted to a Third Party (a "**Compulsory Sublicensee**"), through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party to manufacture, use, sell, offer for sale, import or export a Product in any country in the Territory.

1.22 Confidential Information

The term "Confidential Information" shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**"). Confidential Information shall not include any information, data or know-how that:

(i) was generally available to the public at the time of disclosure, or information that becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,

(ii) can be evidenced by written records to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party,

(iii) is obtained at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

(iv) is developed independently by the Receiving Party or its Affiliates as evidenced by written records other than through knowledge of Confidential Information,

(v) is required to be disclosed by the Receiving Party or its Affiliates to comply with a court or administrative order, provided that the Receiving Party or its Affiliates furnishes prompt notice (in no event less than three (3) days prior to such required disclosure) to the Disclosing Party to enable it to contest such disclosure, or

(vi) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of the Parties.

1.23 Continuation Election Notice

The term "Continuation Election Notice" shall mean the notice Pieris may provide to Roche under Section 19.3.4.

1.24 Control

The term "Control" shall mean (as an adjective or as a verb including conjugations and variations such as "Controls" "Controlled" or "Controlling") (a) with respect to Patent Rights and/or Know-How, the possession by a Party of the ability to grant a license or sublicense of such Patent Rights and/or Know-How without violating the terms of any agreement or arrangement between such Party and any other party and (b) with respect to proprietary materials, the possession by a Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any other party.

1.25 Cover

The term "Cover" shall mean (as an adjective or as a verb including conjugations and variations such as "Covered," "Coverage" or "Covering") that the developing, making, using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would infringe a Valid Claim in the absence of a license under the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

1.26 Effective Date

The term "Effective Date" shall mean December 8, 2015.

1.27 Entry into Portfolio

The term "Entry into Portfolio" shall mean, with regard to a Product, in the case of Roche, the decision by [***] to enter [***], and in the case of Pieris, with regards to a [***], the decision by its [***] to further develop such [***] following confirmation of functionality in vitro.

1.28 EU

The term "EU" shall mean the European Union and all its then-current member countries.

1.29 Event

The term "Event" shall designate a Product and a certain Indication for such Product. Each subsequent Event differentiates itself from the prior Event by either having a different Indication for the same Product, or by being a different Product with the same or a different Indication.

1.30 Expert

The term "Expert" shall mean a person with no less than fifteen (15) years of pharmaceutical industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to product development and/or licensing but excluding any current or former employee or current consultant of either Party. Such person shall be fluent in the English language.

1.31 FDA

The term "FDA" shall mean the Food and Drug Administration of the United States of America.

1.32 FDCA

The term "FDCA" shall mean the Food, Drug and Cosmetics Act.

1.33 Field

The term "Field" shall mean all biopharmaceutical, biomedical and diagnostic uses, including all therapeutic and prophylactic uses.

1.34 Filing

The term "Filing" shall mean the filing of an application by the FDA as defined in the FDCA and applicable regulations, or the equivalent application to the equivalent agency in any other country or group of countries, the official approval of which is required before any lawful commercial sale or marketing of Products.

1.35 First Commercial Sale

The term "First Commercial Sale" shall mean, on a country-by-country basis, the first invoiced sale of a Product to a Third Party by the Roche Group following the receipt of any Regulatory Approval required for the sale of such Product, or if no such Regulatory Approval is required, the date of the first invoiced sale of a Product to a Third Party by the Roche Group in such country.

1.36 FTE

The term "FTE" shall mean a full-time equivalent person-year, taking into consideration statutory holidays and paid annual leave. In no circumstance can the work of any given person exceed one (1) FTE.

1.37 FTE Rate

The term "FTE Rate" shall mean the amount of EUR [***] ([***] Euros) per FTE, on a fully burdened cost basis. Notwithstanding the foregoing, such FTE Rate shall include the costs for [***] not to exceed EUR [***] ([***] Euros) during the Research Term.

1.38 Generated

The term "Generated" means, with respect to a Product, that a plasmid construct was created and expressed in eukaryotic or bacterial cells.

1.39 GLP Tox Study

The term "GLP Tox Study" shall mean a study in accordance with the Good Laboratory Practice (GLP) to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for a product.

1.40 Handle

The term "Handle" shall mean preparing, filing, prosecuting (including interference and opposition proceedings) and maintaining (including interferences, reissue, re-examination, post-grant reviews, inter-parties reviews, derivation proceedings and opposition proceedings).

1.41 HSR

The term "HSR" shall mean the Hart-Scott-Rodino Antitrust Improvements Act.

1.42 ICD

The term "ICD" shall mean the Tenth Revision of the International Classifications of Diseases and Related Health Problems of 2010.

1.43 IFRS

The term "IFRS" shall mean International Financial Reporting Standards.

1.44 Indication

The term "Indication" shall mean a distinct type of disease or medical condition in humans to which a Product is directed and eventually approved. To distinguish one Indication from another Indication, the two Indications have to be (i) listed in two different blocks of the ICD (as a way of example, any neoplasm under C15 is in a different block from any neoplasm under block C16, whereas C15.0 and C15.1 belong to the same block) and (ii) developed by Roche under separate Clinical Studies. Notwithstanding the foregoing, [***] and [***] shall be deemed to be two distinct Indications.

1.45 Initiation

The term "Initiation" or "Initiated" shall mean, with respect to Clinical Studies, the date that a human is first dosed with the Product in a Clinical Study approved by (or allowed by) the respective Regulatory Authority, or, with respect to GLP Tox Studies, the date an animal is first dosed with the Product in a GLP Tox Study approved by (or allowed by) the respective Regulatory Authority.

1.46 Insolvency Event

The term "Insolvency Event" shall mean circumstances under which a Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring); (iv) ceases to carry on business; (v) is unable to pay its debts as they become due in the ordinary course of business.

1.47 Invention

The term "Invention" shall mean an invention that is conceived or reduced to practice in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made (including conceived) by employees of Pieris solely or jointly with a Third Party (a "**Pieris Invention**"), by employees of Roche solely or jointly with a Third Party (a "**Roche Invention**"), or jointly by employees of Pieris and employees of Roche with or without a Third Party (a "**Joint Invention**"). Inventorship shall be determined in accordance with US patent laws.

1.48 JP

The term "JP" shall mean Japan.

1.49 JRC

The term "JRC" shall mean the joint research committee described in Section 6.

1.50 Know-How

The term "Know-How" shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical data, assays, platforms, formulations, specifications, quality control testing data, that are necessary or useful for the discovery, manufacture, development or commercialization of Products.

1.51 Modified Binder

The term "Modified Binder" shall mean a) a [***] alone or b) [***] conjugated and/or fused to each other (such as by a genetic linkage), in the case of a) with, and in the case of b) either with or without modification by conjugation and/or fusion to a moiety, e.g., for [***]. Such [***] may include, without limitation, [***], including [***] based on Roche Technology.

1.52 NDA

The term "NDA" shall mean a new drug application, including all necessary documents, data, and other information concerning a Product, required for Regulatory Approval of the Product as a pharmaceutical product by the FDA or an equivalent application to the equivalent agency in any other country or group of countries (e.g. the marketing authorization application (MAA) in the EU).

1.53 Net Sales

The term "Net Sales" shall mean, for a Product in a particular period, the amount calculated by subtracting from the Sales of such Product for such period: (i) a lump sum deduction of [***] ([***]%) of Sales in lieu of those deductions that are not accounted for on a Product-by-Product basis (*e.g.*, freight, postage charges, transportation insurance, packing materials for dispatch of goods, custom duties); (ii) actual uncollectible amounts accrued during such period and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Product for such period; (iii) credit card charges (including processing fees) accrued during such period on such Sales; and (iv) government mandated fees and taxes and other government charges accrued (but excluding taxes based on the income of the selling party) during such period not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body. For clarity, no deductions taken in calculating Sales under Section 1.71 may be taken a second time in calculating Net Sales.

1.54 Party

The term "Party" shall mean Pieris or Roche, as the case may be, and "Parties" shall mean Pieris and Roche collectively.

1.55 Patent Rights

The term "Patent Rights" shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part of any of the foregoing.

1.56 Phase I Study

The term "Phase I Study" shall mean a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.57 Phase II Study

The term "Phase II Study" shall mean a human clinical trial, for which the primary endpoints include a determination of dose ranges and/or a preliminary determination of efficacy in patients being studied as described in 21 C.F.R. § 312.21(b) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.58 Phase III Study

The term "Phase III Study" shall mean a human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in a manner sufficient to obtain regulatory approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.59 Phase-out Binder

The term "Phase-out Binder" shall mean an Anticalin® discovered [***] that [***] the Target.

1.60 Phase-out Term

The term "Phase-out Term" shall mean the period beginning [***] provided that Roche has opted for [***] as described in Section 10.3.1, and ending [***] if Roche has paid [***] and beyond the [***], the [***], if applicable as per Sections 10.3.1. and 10.3.2.

1.61 Pieris IP

The term "Pieris IP" shall mean Know-How and Patent Rights that Pieris owns or Controls (i) as of the Effective Date, which include Patent Rights listed in Appendix 1.60; and (ii) during the Agreement Term that are necessary or useful for the discovery, manufacture, development or commercialization of an Anticalin®, or that are relating to Pieris Technology.

1.62 Pieris Technology

The term "Pieris Technology" shall mean Anticalin Libraries, Anticalin Selection, Anticalin Expression and Anticalin Affinity Maturation methods.

1.63 Product

The term "Product" shall mean any product or composition containing at least one [***], regardless of their finished forms or formulations or dosages. With regard to milestone and royalty payments, a Product shall differentiate itself from another Product by containing, in addition to at least [***], a [***] ([***]) as active ingredient that binds to [***]. Examples: 1) [***] developed as separate products are considered the same Product; 2) a [***] and a [***] a pharmaceutically active molecule that [***] are considered two distinct Products.

1.64 Regulatory Approval

The term "Regulatory Approval" shall mean any approvals, licenses, registrations or authorizations by Regulatory Authority, necessary for the sale of a Product in the Field in a regulatory jurisdiction in the Territory.

1.65 Regulatory Authority

The term "Regulatory Authority" shall mean any national, supranational (e.g., the European Commission, the Council of the European Union, the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity including the FDA, in each country involved in the granting of Regulatory Approval for the Product.

1.66 Research Plan

The term "Research Plan" shall mean the plan of research attached as Appendix 1.66 outlining the work expected to be performed by Pieris and Roche, as such plan may be updated from time to time as permitted in this Agreement.

1.67 Roche Group

The term "Roche Group" shall mean collectively Roche, its Affiliates and its Sublicensees.

1.68 Roche IP

The term "Roche IP" shall mean Know-How and Patent Rights that Roche owns or Controls as of the Effective Date and during the Agreement Term and that relate to Roche Technology. For purposes of clarity, the Patent Rights identified in Appendix 1.68 ("**Excluded Patent Rights**") are specifically excluded from the Roche IP.

1.69 Roche Technology

The term "Roche Technology" shall mean Roche's [***] to be [***] with the [***] or [***] for [***].

1.70 Royalty Term

The term "Royalty Term" shall mean, with respect to a Product and for a given country, the period of time commencing on the date of First Commercial Sale of the Product in such country and ending on the later of the date that is (a) [***] after the date of the First Commercial Sale of the Product in such country, or (b) the expiration of the last to expire Composition of Matter Claim of a patent owned or Controlled by [***] (or [***]) in such country Covering the use, import, offering for sale, or sale of the Product. With regard to the countries of the EU, the [***] period shall for each country begin at the earlier of (i) date of First Commercial Sale in the specific country or (ii) date of First Commercial Sale in [***] ([***]). For clarity, any Composition of Matter Claim Covering only [***] that [***] and which is comprised within Product shall not be relevant for determining the Royalty Term.

1.71 Sales

The term "Sales" shall mean, for a Product in a particular period, the sum of (i) and (ii):

(i) the amount stated in the Roche Holding AG "Sales" line of its externally published audited consolidated financial statements with respect to such Product for such period (excluding sales to any Sublicensees that are not Affiliates of Roche). This amount reflects the gross invoice price at which such Product was sold or otherwise disposed of (other than for use as clinical supplies or free samples) by Roche and its Affiliates to such Third Parties (excluding sales to any Sublicensees that are not Affiliates of Roche) in such period reduced by gross-to-net deductions, if not previously deducted from such invoiced amount, taken in accordance with the then currently used IFRS, to the extent any of such gross-to-net deductions are actually allowed.

By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following:

(a) credits, reserves or allowances granted for (i) damaged, outdated, returned, rejected, withdrawn or recalled Product, (ii) wastage replacement and short-shipments; (iii) billing errors and (iv) indigent patient and similar programs (*e.g.*, price capitation);

(b) governmental price reductions and government mandated rebates;

(c) chargebacks, including those granted to wholesalers, buying groups and retailers;

(d) customer rebates, including cash sales incentives for prompt payment, cash and volume discounts; and

(e) taxes and any other governmental charges or levies imposed upon or measured by the import, export, use, manufacture or sale of a Product (excluding income or franchise taxes).

For purposes of clarity, sales by Roche and its Affiliates to any Sublicensee shall be excluded from "Sales", but a subsequent sale to Third Parties by such Affiliate or Sublicensee shall be deemed a "Sale".

(ii) for Sublicensees that are not Roche Affiliates (and excluding Compulsory Sublicensees), the sales amounts reported to Roche and its Affiliates in accordance with the sublicensee contractual terms and their then-currently used accounting standards. For the purpose of clarity, any such Sublicensee sales as reported to Roche in accordance with Compulsory Sublicense agreements shall be excluded from the sales amount.

1.72 Selected Binder

The term "Selected Binder" shall mean a [***] or [***] that originates from the pool of Binders discovered by screening any Pieris Anticalin Library, that may have undergone lead optimization, and is then selected by Roche for incorporation into a Product. At its discretion, Roche can select [***] or [***] during the [***] or [***] and shall be free to [***] or [***] during such period, with such [***] to be [***]

1.73 Sublicensee

The term "Sublicensee" shall mean an entity to which Roche has licensed any right (through one or multiple tiers), other than through a Compulsory Sublicense, pursuant to this Agreement.

1.74 Target

The term "Target" shall mean the biological target of a pharmacologically active drug compound. For this collaboration the [***] Target is [***] as described in Appendix 1.74.

1.75 Territory

The term "Territory" shall mean all countries of the world.

1.76 Third Party

The term "Third Party" shall mean a person or entity other than (i) Pieris or any of its Affiliates or (ii) a member of the Roche Group.

1.77 US

The term "US" shall mean the United States of America and its territories and possessions.

1.78 Valid Claim

The term "Valid Claim" shall mean a claim in any unexpired and issued Patent Rights that has not been disclaimed, revoked or held invalid by a final non-appealable decision of a court of competent jurisdiction or government agency.

1.79 Additional Definitions

Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	Section
Accounting Period	11.1
Acquired Party	19.2.3
Alliance Director	6.8
Annual Exclusive Target Access Fee	10.3.1
Bankruptcy Code	20
[***]	2.4
Breaching Party	19.2.1
Chairperson	6.2
Chugai	1.1
Companion Diagnostic Product	10.4
Compulsory Sublicensee	1.21
Development Event	10.4 (in table)
Disclosing Party	1.22
Excluded Patent Rights	1.68
Expert Committee	10.7
First Sales Based Event	10.5
Foundation	1.1
Indemnified Party	16.3
Indemnifying Party	16.3
Joint Invention	1.47
Members	6.2

Definition	Section
Non-Acquired Party	19.2.3
Non-Breaching Party	19.2.1
Patent Term Extensions	14.11
Payment Currency	11.3
Peremptory Notice Period	19.2.1
[***]	10.3.2
Pieris Invention	1.47
Progress Reports	3.1.5
Publishing Notice	18.4
Publishing Party	18.4
Receiving Party	1.22
Reference Product Sponsor	14.10
Relative Commercial Value	10.7
Research Records	3.1.6
Research Term	3.1.4
Roche Invention	1.47
Roche Valid Claim	19.3.4 (b)
Samples	19.3.4 (b)
SEC	1.9
Second Sales Based Event	10.5
Sensitive Information	19.2.3
SPCs	14.11
Stand-alone Diagnostic Product	10.4
Third Sales Based Event	10.5

2. Grant of License

2.1 Research Licenses

Roche grants to Pieris during the Research Term a non-exclusive right and license under Roche IP that are necessary or useful for the discovery, manufacture or development of [***] solely to enable Pieris to perform the activities contemplated under the Research Plan under this Agreement.

Pieris grants to Roche during the Agreement Term an exclusive (even as to Pieris except for activities performed under the Research Plan and, if applicable, [***] for Roche) right and license under Pieris IP that are necessary or useful for the discovery, manufacture or development of [***] and Products, in particular to enable Roche to identify and evaluate [***] in order to enable selection of [***].

2.2 Commercial License to Roche

Pieris hereby grants to Roche an exclusive (even as to Pieris) right and license, including the right to sublicense through multiple tiers, under Pieris' interest in the Pieris IP to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold Products in the Field in the Territory.

2.3 Sublicense

Roche shall have the right to sublicense or subcontract (through multiple tiers); provided, however, that in the event of such sublicensing, (a) such Sublicensees will be subject to the same confidentiality and diligence obligations Roche has hereunder, and (b) Roche will remain liable for all the terms and conditions of this Agreement.

2.4 License to Pieris after Phase-out Term

After expiration of the Phase-out Term and with respect to Target, Roche grants Pieris (subject to Roche's right of first negotiation as defined below) a non-exclusive license, including the right to sublicense through multiple tiers, under Roche's Patent Rights on Inventions made under the Agreement. Said license shall be limited to such Inventions (a) made (including conceived) during the time period starting at the Effective Date and ending [***] and (b) related to [***] to:

(i) Select binders from the hits obtained [***], performed after [***], of the Anticalin Libraries, that – per each individual binder – contain [***] in the amino acid positions that Pieris randomizes in its Anticalin Libraries (in comparison to the amino acid sequence of the respective wild type lipocalin; for clarity, this means [***] depending on the Anticalin Library used) as compared to [***] and

(ii) On the basis of binders obtained under (i) above, research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell and have sold products that, in addition to [***] and which would infringe such Roche's Patent Rights but for a license granted hereunder ("**[*****]**"), in the Field in the Territory. [***] may not bind to the [***] as [***] for which [***] has [***] and is developing using Commercially Reasonable Efforts at the time Pieris initiates an independent screening campaign as described under (i) above for a [***]. Pieris shall have the right to make a written query to Roche's alliance manager (to be communicated by Roche in the annual reports under Section 6.11) in order to find out if [***] has [***] with regard to a [***], which query shall be answered within thirty (30) days. For clarity, the license granted by Roche to Pieris for a [***] shall be maintained even in the situation where Roche has, subsequent to Roche granting the license hereunder, [***], provided, however, that Pieris has used Commercially Reasonable Efforts to [***]. For further clarity, the above license is limited to [***] and does not include [***]. Pieris shall inform Roche in writing about all [***] for which it has reached [***] within thirty (30) days after such [***] has been reached. Furthermore, Pieris shall annually inform Roche on the development progress of such [***] until completion of the first Phase II Study.

Example 1: If Pieris makes a query for a specific [***] (i.e., [***]), and Roche has reached [***], then no license is granted to Pieris.

Example 2: If Pieris makes a query for a specific [***] (i.e. [***]), and Roche has reached [***] (i.e., [***]) that [***], then no license is granted to Pieris.

Further, the above license is subject to Roche's right of first negotiation along the following lines: (i) if either Pieris decides to seek a licensing partnership with a third party with regards to a [***], or to sell such [***] to a third party (for clarity, a Change of Control of Pieris shall not be deemed a sale of such [***]), or a [***] that has not been partnered or sold has completed the first Phase II Study, it shall provide written notice of such intent to Roche; (ii) Roche shall then have [***] to request access to any information Pieris' has with regard to such [***]; (iii) in case Roche does request such access, then Roche shall have [***] after Pieris has granted to Roche

access to the relevant and complete files and provided corresponding information to Roche to decide whether it wants to develop and commercialize such [***] itself and to provide a corresponding written notice to Pieris of its intent to do so; (iv) in case Roche does provide such written notice, then Roche shall have the exclusive right to negotiate an agreement with Pieris with regard to such [***], under terms to be negotiated in good faith and such agreement to be put in writing within [***] of Roche's written notification to Pieris of its intent to develop and commercialize such [***] itself (hereinafter called "Negotiation Period"). If Roche and Pieris fail to agree upon the terms and conditions for such agreement during the Negotiation Period, Pieris will be free to enter into a transaction regarding such [***] with any Third Party; provided that Pieris shall not enter into an agreement with any Third Party on financial terms and conditions that are more favourable for the Third Party when taken in their totality than the terms and conditions last offered in writing by Roche to Pieris during the Negotiation Period. Notwithstanding the foregoing, if Pieris intends to enter into a partnership to Generate [***] (i.e., that have not been Generated at the time of notification from Pieris), Roche shall only have [***] from receipt of such notification under (i) to assess and decide if it wants to request negotiations under (iv). In other words, the procedures foreseen in (ii) and (iii) of this paragraph shall in total [***].

3. Research Collaboration

3.1.1 Scope

The execution of the Research Plan shall begin on [***]. During the Research Term, Pieris commits, subject to FTE funding by Roche, to an average of [***] as specified in the Research Plan and adjusted as necessary by the JRC from time to time, allowing the generation and testing of [***] against the Target, the generation and testing of [***] and Products, as well as any other activities to be performed according to the Research Plan. The criteria for successfully completing the Research Plan and handing over the deliverables are defined in the Research Plan. The activities conducted in connection with the Research Plan will be overseen by the JRC.

3.1.2 Diligent Efforts

Roche and Pieris shall each use Commercially Reasonable Efforts to perform their respective tasks and obligations in conducting all activities ascribed to it in the then-current Research Plan, in accordance with the time parameters set forth therein.

3.1.3 Research Plan

The Parties will conduct the research in accordance with the Research Plan. In alignment with Section 6.3, the Research Plan will be updated as needed by the JRC, with such updates to be documented in an updated Research Plan as part of the applicable JRC Minutes. The Research Plan will set forth (i) the scope of the research and the resources that will be dedicated to the activities contemplated within the scope of the research, including the responsibilities of each Party, (ii) specific objectives for each Research Plan task, which objectives will be updated or amended, as appropriate, by the JRC as research progresses, and (iii) budgets for such activities.

3.1.4 Research Term

The Research Term shall commence on [***] and shall continue for [***] unless extended by Roche by providing written notice to Pieris no later than [***] prior to the end of the initial term and subject to further FTE funding for a period up to [***]. If at the end of the Research Term (including any extension) the original objectives of the Research Plan are not met and Roche could not choose [***] for product development, the Parties shall agree on whether to further extend the Research Term and the share of funding by each Party.

3.1.5 Progress Reports

At least quarterly during the Research Term, Pieris shall have the obligation to prepare and provide to the JRC a detailed written report summarizing the progress of the work performed by Pieris under the Research Plan during the preceding Calendar Quarter. Promptly upon expiry of the Research Term, Pieris shall provide a final written report summarizing its activities under the Research Plan and the results thereof. Upon the written request of Roche and not more than once in each Calendar Year, Pieris shall permit Roche, at Roche's expense, to have access during normal business hours to those records of Pieris that may be necessary to verify the basis for any payments hereunder.

3.1.6 Research Records

Each Party shall maintain records regarding the execution of the Research Plan (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of the Research Plan.

3.1.7 Work on Target by Pieris

During the Research Term and, if applicable, the [***], Pieris shall work exclusively with Roche to identify and discover molecules that inhibit or specifically bind to the Target. For the avoidance of doubt, this obligation also precludes Pieris from working on the Target under its own independent research. In case Pieris undergoes a Change of Control and the Change of Control Group has or puts in place a research program targeting the Target, or if Pieris takes over control of a Third Party having such a research program, then Pieris shall put or have put in place appropriate fire walls in order to avoid any spillover of information regarding the Research Plan and associated Progress Reports, Research Records and Confidential Information received from Roche under this Agreement outside of the organisation of Pieris that exists before such Change of Control or take over takes place. Pieris may not perform work on Pieris Technology with regard to Target except as provided for under this Agreement (including, for clarity, as described under Section 2.4).

4. Diligence

4.1 In General

Roche and Pieris shall use Commercially Reasonable Efforts to perform their respective activities contemplated by this Agreement or as may be agreed upon in any subsequent written agreements with respect to the subject matter hereof, including but not limited to any activities under the Research Plan. Specifically, Roche agrees to use Commercially Reasonable Efforts to pursue development and commercialization of Products in the Field in the Territory, which

minimally shall require that Roche shall seek to market at least one Product in [***] and in [***] ([***]). Notwithstanding anything to the contrary in this Agreement, Roche shall be deemed to not be using Commercially Reasonable Efforts, if, for whatever reason, it completely ceases all research, development or commercialization activities on all Products for a period longer than [***] during the Agreement Term.

4.2 Diligence of Roche prior to Initiation of Phase III Study

If Roche or any of its Affiliates (i) acquires (e.g., by way of in-license or acquisition) a product targeting the Target for which [***], or (ii) internally develops a product targeting the Target for which [***], and that for (i) and (ii) does not utilize Pieris Technology, then, for as long as such competing product is more advanced than the first Product, Roche shall and shall ensure that its Affiliates with regards to any first Product commit to the following timelines: (a) Initiation of first GLP Tox Study within [***], (b) Initiation of first Phase I Study within [***], (c) Initiation of first Phase II Study within [***], or, if such timelines are not deemed appropriate by Roche, and Roche provides acceptable reasons for delays as reasonably accepted by Pieris, such timelines may be extended by mutual written agreement. The diligence obligation under this Section 4.2 expires when such acquired or internally developed product is terminated.

4.3 Limits

For clarity, the foregoing limitations on acquiring or internally developing products targeting the Target as described in Section 4.2 shall not apply to [***] of the [***] or [***] or that are [***] or [***], for as long as [***].

5. Development

5.1 Development by Roche

After a [***] has been transferred from Pieris to Roche as specified in the Research Plan, Roche, at its sole cost, shall be responsible for pursuing pre-clinical and clinical development of Products, subject to the terms of this Agreement.

5.2 Provision of Information

Pieris shall disclose and make available to Roche (i) all data and information developed under the Research Plan, and (ii) all additional data and information that Pieris reasonably believes are necessary to conduct development of Products. Pieris, through the JRC, shall answer any questions reasonably posed and provide any information reasonably requested. Notwithstanding the foregoing, Pieris shall not be obligated to disclose any confidential information received from a Third Party to Roche.

6. Governance

6.1 Joint Research Committee

Within sixty (60) days after the Effective Date of this Agreement, the Parties shall establish a JRC to oversee the development activities under this Agreement.

6.2 Members

The JRC shall be composed of four (4) persons ("**Members**"). Roche and Pieris each shall be entitled to appoint two (2) Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a Member shall notify the other Party at least ten (10) days prior to the next scheduled meeting of the JRC. Both Parties shall use reasonable efforts

to keep an appropriate level of continuity in representation. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole JRC meeting with prior notification to the JRC. Members may be represented at any meeting by another person designated by the absent Member. The JRC shall be chaired by a Roche Member ("**Chairperson**").

6.3 Responsibilities of the JRC

The JRC shall have the responsibility and authority to:

a) approve the Research Plan;

b) review and revise the Research Plan;

c) oversee the execution of the Research Plan;

d) establish timelines and criteria for decision points;

e) determine whether success- and other criteria have been met;

f) evaluate [***]

g) review the efforts of the Parties and allocate those resources for the Research Plan (including the budget);

h) identify and agree on the appropriate resources (including FTE staffing requirements) necessary to conduct the Research Plan;

i) establish a touch point site or similar tool to enable secured exchange of data generated under the Research Plan

j) monitor and implement the transfer of the [***], both in terms of material available at Pieris and the corresponding amino acid and nucleic acid sequences, and any associated data generated under the Research Plan to Roche;

k) monitor the number of FTE funding and adaptation of such number as necessary as set forth in Section 3.1.1;

l) recommend action items to its respective decision making bodies;

m) in a JRC meeting towards the end of the Research Term, list the materials and information to be provided by Pieris to Roche according to Section 10.3.1;

n) attempt to resolve any disputes on an informal basis;

o) determine the mechanism of project information exchange, including project team meetings.

The JRC shall have no responsibility and authority other than that expressly set forth in this section or otherwise expressly provided in this Agreement.

6.4 Meetings

The Chairperson or his/her delegate is responsible for sending invitations and agendas for all JRC meetings to all Members at least ten (10) days before the next scheduled meeting of the JRC. The venue for the meetings shall be agreed by the JRC. The JRC shall hold meetings at least twice per calendar year, either in person or by tele-/video-conference (but at least once per year in person), and in any case as frequently as the Members of the JRC may agree shall be necessary, but not more than four times a year. The Alliance Director of each Party may attend the JRC meetings as a permanent participant and may be a JRC Member.

6.5 Minutes

The Chairperson is responsible for designating a Member to record in reasonable detail and circulate draft minutes of JRC meetings to all members of the JRC for comment and review within twenty (20) days after the relevant meeting. The Members of the JRC shall have ten (10) days to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the JRC within thirty-five (35) days of the relevant meeting. The Chairperson approves the final version of the minutes before its distribution.

6.6 Decisions

6.6.1 Decision Making Authority

The JRC shall decide matters within its responsibilities set forth in Section 6.3.

6.6.2 Consensus; Good Faith

The Members of the JRC shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by the JRC. The Parties shall endeavor to make decisions by consensus.

6.6.3 Failure to Reach Consensus

If the JRC is unable to decide a matter by consensus, then Roche shall have the final decision authority on any matter. However, a unilateral decision by Roche shall not result in any material change of the day to day use or operational allocation of Pieris' personnel, equipment and resources, or in any material increase in the overall level of resources to be committed by Pieris to the Research Plan unless Roche compensates Pieris accordingly.

6.7 Information Exchange

Pieris and Roche shall exchange the information in relation to their activities under the Research Plan through the JRC and Pieris and Roche may ask reasonable questions in relation to the above information and offer advice in relation thereto. The JRC may determine other routes of information exchange.

6.8 Alliance Director

Each Party shall appoint one person to be the point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties (each, an "**Alliance Director**"). The Alliance Directors may participate in the JRC meetings. The Alliance Directors shall facilitate resolution of potential and pending issues and potential disputes to enable the JRC to reach consensus and avert escalation of such issues or potential disputes.

6.9 Limitations of Authority

The JRC shall have no authority to amend or waive any terms of this Agreement.

6.10 Expenses

Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with the JRC.

6.11 Lifetime

The JRC shall exist until the [***]. Thereafter, Roche shall provide Pieris annual reports describing in reasonable detail the development and commercialization progress of the Product(s), including [***] in Roche's opinion (these include activities related to milestone achievements under this Agreement).

7. Supply

7.1 Clinical Supply of Product(s)

Roche shall be responsible at its own expense for the manufacture and supply of clinical supplies of the Product(s).

7.2 Commercial Supply of Product(s)

Roche shall be solely and exclusively responsible at its own expense for the commercial manufacture and commercial supply of Product(s) for sale in the Territory, either by itself or through Third Parties.

7.3 Provision of Information

Pieris shall disclose and make available to Roche all additional data and information that Pieris reasonably believes are necessary or useful to manufacture and supply the Product(s).

8. Regulatory

8.1 Responsibility

Roche, at its sole cost, shall pursue all regulatory affairs related to Product(s) in the Territory including the preparation and filing of applications for regulatory approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Products. Roche shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for all Products in all countries in the Territory. Roche or its Affiliates shall own and file in their discretion all regulatory filings and regulatory approvals for all Products in all countries of the Territory.

Roche, at its sole cost, shall report to appropriate authorities in accordance with local requirements all adverse events related to use of the Products in the Territory.

9. Commercialization

9.1 Responsibility

Roche, at its own expense, shall have sole responsibility and decision making authority for the marketing, promotion, sale and distribution of Products in the Territory.

9.2 Updates to Pieris

Upon request of Pieris, Roche shall update Pieris regarding the commercialization of the Product in the Territory in the Field by Roche, its Affiliates and Sublicensees. If Pieris requests an update, Roche shall provide a high level summary, in writing and/or through a meeting (face to face/ tele-presence/videoconference or telephone). Pieris shall not request an update more frequently than [***].

10. Payment

10.1 Initiation Payment

Within thirty (30) days after the Effective Date and receipt of an invoice from Pieris, Roche shall pay to Pieris six and a half million Swiss francs (CHF 6,500,000).

10.2 Research Costs

During the Research Term, Roche shall fund the work to be performed at Pieris for the Research Plan at the FTE Rate as specified in the Agreement.

Roche shall pay to Pieris such work to be performed during the Research Term, [***], within [***] after receiving a corresponding invoice from Pieris, corresponding to the [***] for such [***] according to the Research Plan (as it may be amended from time to time through the JRC). Within thirty (30) days after the end of each Calendar Quarter during the Research Term, Pieris shall provide to Roche a document specifying [***] and [***] incurred by Pieris during such Calendar Quarter. Any overpayment from Roche shall be credited to the invoice for the next quarter. Any underpayment from Roche shall be added to the invoice for the next quarter.

10.3 [***] Fee and [***] Fee

10.3.1 Annual Exclusive Target Access Fee

When (i) all [***] have been transferred to Roche, including material available at Pieris, information on the corresponding amino acid and nucleic acid sequences, and any relevant associated data generated under the Research Plan in accordance with the final report under Section 3.1.5 (excluding the [***]) and as specified by the JRC in accordance with Section 6.3 (m), and Roche has confirmed the receipt of all materials, information and the final report as per 3.1.5 (such confirmation not to be unduly delayed), and (ii) [***] has ended, then Roche shall have [***] to exercise its option to [***] as specified in [***] by giving written notice to Pieris. If Roche provides such written notice, it shall pay to Pieris an [***] as specified in this Section ("**[***]**"). In case Roche opts for such [***], then Roche shall have the right to terminate such [***] at the end of each anniversary date of the end of the Research Term, by providing written notice to Pieris at the latest [***] prior to such anniversary.

The [***] Fee shall be, if applicable:

a) for each of the [***] following the end of the [***]:

CHF [***].

b) for each of the [***] following the end of the [***]:

CHF [***].

10.3.2 [***]If Roche has opted for [***] as described in Section 10.3.1 above, then Roche shall pay to Pieris an additional [***] ("**[***]**") if (i) Roche does not terminate [***] as described in Section 10.3.1 before the [***] of the end of the [***] and (ii) Roche has [***] with regard to the first Product reaching this development stage within [***] of expiry of the [***].

The [***] shall be, if applicable:

a) for the [***] following the end of the [***]:

CHF [***].

b) for the [***] following the end of the [***]:

CHF [***].

The [***] will be paid in addition to the [***] (if applicable) for the [***] following the end of the [***]. Roche shall pay to Pieris amounts due under this Section 10.3 within [***] from receipt of the correct invoice from Pieris.

10.4 Development Event Payments

For Products Generated during [***] (the [***] shall be deemed to be (i) [***], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least [***]), Roche shall pay to Pieris the following one-time payments at the following respective amounts for the applicable Development Events (as listed in the table below) upon reaching the respective Development Event:

Development Event	first Event ([***] CHF)	[***] ([***] CHF)	[***] ([***] CHF)
Initiation of GLP Tox Study	[***]	[***]	[***]
Initiation of Phase I Study	[***]	[***]	[***]
Initiation of Phase II Study	[***]	[***]	[***]
Initiation of Phase III Study	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
NDA Filing [***]	[***]	[***]	[***]
First Commercial Sale [***]	[***]	[***]	[***]
First Commercial Sale [***]	[***]	[***]	[***]
First Commercial Sale [***]	[***]	[***]	[***]
Total	[***]	[***]	[***]

* Payments for a [***] of a Product shall be payable upon achievement of Regulatory Approval in the respective portion of the Territory.

The amounts specified in the table immediately above shall be reduced by [***] for Products Generated during the [***]. For clarity, the respective Development Event shall be deemed to have been paid in full, even if such reduction applies. For Products Generated later than [***], no milestone payments shall be paid.

For clarity, the total potential development event payments for a first Event shall not exceed [***] Swiss francs (CHF [***]), the total potential development event payments for each of a [***] shall not exceed [***] Swiss francs (CHF [***]), the total potential development event payments for each of a [***] shall not exceed [***] Swiss francs (CHF [***]), and in no case shall the total development event payments paid to Pieris under this Section exceed [***] Swiss francs (CHF [***]). In case[***] and/or [***] is not [***], then the [***]and/or [***] becomes [***] and/or [***] with regard to[***] to the extent of the [***], and [***] with regard to the [***] and/or [***]. Payments with regards to a Development Event for a [***], respectively, are payable only once under this Agreement, upon the first occurrence of the applicable Development Event irrespective of the number of times such Development Event may subsequently occur through the development of a subsequent Product and/or Indication.

Example: [***].

Upon reaching Development Events, Roche shall timely notify Pieris and Development Event payments shall be paid by Roche to Pieris within [***] from occurrence of the applicable event and receipt of a correct invoice from Pieris.

Notwithstanding anything contained in this Section 10.4, no development event payments shall be paid to Pieris in the event that a Product is itself developed as a companion diagnostic, i.e. for predicting and/or monitoring the response of a human being to treatment with another Product (e.g. as a biomarker that is used to detect or quantify the presence or amount of Target in body or tissue; such Product a "**Companion Diagnostic Product**"). The same rule shall apply (no development event payments) in case a Product is developed as a stand-alone diagnostic product, i.e. for detecting the presence and/or quantifying the amount of Target in body fluids or tissue ("**Stand-alone Diagnostic Product**").

10.5 Sales Based Events

Roche shall pay to Pieris the following one-time sales based event payments as specified in the table below (First Sales Based Event, Second Sales Based Event, Third Sales Based Event) up to a total of [***] Swiss francs (CHF [***]) at the following respective amounts for the applicable events for the first Product to achieve the following levels of Net Sales:

	Payment	
Net Sales Threshold	**if Product is Generated during [***]***	**if Product is Generated during [***]***
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] ("**First Sales Based Event**")	CHF [***]	CHF [***]
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] ("**Second Sales Based Event**")	CHF [***]	CHF [***]
First Calendar Year in which worldwide calendar year Net Sales of a Product exceed CHF [***] ("**Third Sales Based Event**")	CHF [***]	CHF [***]

* The [***] shall be deemed to be (i) [***] for [***], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least [***].

For Products Generated later than [***], no milestone payments shall be paid.

Each of the sales based event payments shall be paid no more than once during the Agreement Term, at first occurrence of the event for the Product in the Territory first reaching the respective Net Sales Threshold, irrespective of whether or not the previous sales based event payment was triggered by the same or by a different Product, and shall be non-refundable, and shall be paid within [***] after the end of the Calendar Year in which the event first occurs.

Notwithstanding anything contained in this Section 10.5, no sales event payments shall be paid to Pieris in the event that a Product is itself developed, used and commercialized as a Companion Diagnostic Product or as a Stand-alone Diagnostic Product.

10.6 Royalty Payments

10.6.1 Royalty Term

Royalties shall be payable by Roche on Net Sales of Products on a Product-by-Product and country-by-country basis until the expiry of the Royalty Term. Thereafter, the licenses granted to Roche shall be fully paid up, irrevocable, and royalty-free.

10.6.2 Royalty Rates

Roche shall, on a Product-by-Product basis, for any Product that was Generated during [***] (the [***] shall be deemed to be (i) [***] for [***], and (ii) for any other Product as long as specified in Section 1.60, but in any event at least [***]), pay to Pieris royalties by applying the following royalty rates on Calendar Year Net Sales of a given Product in the Territory as follows:

Tier of Calendar Year Net Sales in CHF of a Product:	**Percent (%) of Net Sales:**
Up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales and up to CHF [***] Net Sales	[***]
More than CHF [***] Net Sales	[***]

For Products Generated during [***], Roche shall pay royalties to Pieris by applying [***] of the applicable royalty rate specified in this Section. For Products Generated later than [***], no royalty payments shall be paid.

10.6.3 Royalty Reductions

For the purpose of calculating royalties of a Product, Calendar Year Net Sales and the royalty rates shall be subject to the following adjustments, as applicable:

10.6.3.1 No Valid Claim

If no Composition of Matter Claim of a patent owned or Controlled by Roche exists in a given country Covering the use, import, offering for sale, or sale of the Product, or if such claim that previously existed loses its validity during the applicable Calendar Year, then the royalty payments due to Pieris for such Product in such country shall be reduced by [***].

10.6.3.2 Biosimilar Product

Upon the first entry in a given country of a Biosimilar Product, the royalties in such country for such Product shall be reduced as follows:

a) If in any Calendar Quarter after entry of a Biosimilar Product there has been a decline of the Net Sales of the applicable Product in such country greater than [***] of the level of the Net Sales of such Product achieved in the two consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to Pieris for such Product in such country shall be reduced by [***] for the remainder of the Royalty Term as from such Calendar Quarter.

b) If in any Calendar Quarter after entry of a Biosimilar Product there has been a decline of the Net Sales of the applicable Product in such country greater than [***] of the level of the Net Sales of such Product achieved in the two consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to Pieris for such Product in such country shall end as from such Calendar Quarter and no royalties shall be due by Roche in such country for such Product, and the license in that country for such Product shall be fully paid-up and irrevocable.

10.6.4 Products used as Diagnostics

Notwithstanding anything contained in this Section 10.6, no royalty payments shall be paid to Pieris in the event that a Product is itself developed, used and commercialized as a Companion Diagnostic Product.

In case a Product is developed, used and commercialized as a Stand-alone Diagnostic Product, the Parties shall agree on royalties to be paid on Net Sales of such Product in good faith, but in any case lower than those specified in this Section.

10.7 Combination Product

If Roche or its Affiliates intend to sell a Combination Product, then the Parties shall meet approximately [***] prior to the anticipated First Commercial Sale of such Combination Product in the Territory to negotiate in good faith and agree to an appropriate adjustment to Net Sales to reflect the relative commercial value contributed by the components of the Combination Product (the "**Relative Commercial Value**"). If, after such good faith negotiations not to exceed [***], the Parties cannot agree to an appropriate adjustment, the dispute shall be initially referred to the executive officers of the Parties in accordance with Section 21.2. Should the Parties fail to agree [***] of such referral, then the Relative Commercial Value shall be determined by an Expert Committee under the procedures of this Section.

If the Parties are unable to agree on the Relative Commercial Value, then Roche will select one (1) individual who would qualify as an Expert, Pieris will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairman of a committee of the three Experts (the "**Expert Committee**"), each with a single deciding vote. The Expert Committee will promptly hold a meeting to review the issue under review, at which it will consider memoranda submitted by each Party at least [***] before the meeting, as well as reasonable presentations that each Party may present at the meeting. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide on issues outside the scope mandated under terms of this Agreement.

Notwithstanding the foregoing, for any Combination Product that includes a Companion Diagnostic Product (i.e., not a Companion Diagnostic), the Relative Commercial Value of such Companion Diagnostic Product shall be [***]

10.8 Third Party Payments

With the exception of Pieris IP, Roche shall be responsible for and pay or have paid any consideration owed to any Third Party in relation to Third Party intellectual property rights. Roche shall have the right to deduct a maximum of

a) [***], if such Third Party intellectual property rights Cover the [***] in such Product; or

b) [***] if such Third Party intellectual property rights Cover any other part of the Product, provided, however, that no such [***] reduction shall apply if (i) such Third Party intellectual property rights Cover a molecule targeting an antigen other than the Target and such molecule is part of a Combination Product whose sales have been deducted from Net Sales per Section 10.7, or (ii) such Third Party intellectual property rights Cover Roche Technology existing as of the Effective Date and used in the Product;

of such consideration actually paid to a Third Party from any payments otherwise due and payable by Roche to Pieris under this Agreement. Any such deduction shall be permitted on a Product-by-Product and country-by-country basis. In no event shall the amount of royalties payable to Pieris for a given Calendar Year be reduced to lower than [***] of the royalties otherwise due for the Net Sales of such Product for the applicable Calendar Year as a result of deductions made under this Section.

10.9 Disclosure of Payments

Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as may be advisable or required under Applicable Law, including the US Sunshine Act.

11. Accounting and reporting

11.1 Timing of Payments

Roche shall calculate royalty payments set forth in Section 10.6 quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of a reporting period). Roche shall pay such payments quarterly within [***] after the end of each reporting period in which Net Sales occur.

11.2 Late Payment

Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at [***] above the average one-month Euro Interbank Offered Rate (EURIBOR), as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

11.3 Method of Payment

Royalties on Net Sales and all other amounts payable by Roche hereunder shall be paid by Roche in Swiss francs (the "**Payment Currency**") to account(s) designated by Pieris, except Research Costs according to Section 10.2 which shall be paid to such account(s) in Euros.

11.4 Currency Conversion

When calculating the Sales of any royalty-bearing Product that occur in currencies other than the Payment Currency, Roche shall convert the amount of such sales into the Payment Currency using Roche's then-current internal foreign currency translation actually used on a consistent basis in preparing its audited financial statements (at the Effective Date, YTD average rate as reported by Reuters).

11.5 Reporting

With each payment Roche shall provide Pieris in writing for the relevant Calendar Quarter on a Product-by-Product and [***] (i.e. [***]) basis the following information:

a) Sales in the Payment Currency;

b) Net Sales in the Payment Currency;

c) adjustments made pursuant to Section 10.7*;*

d) Net Sales in the Payment Currency after adjustments made pursuant to Section 10.7 in the Payment Currency;

e) royalty rate pursuant to Section 10.6.2;

f) adjustments made pursuant to Sections 10.6.3 and 10.8; and

g) total royalty payable in the Payment Currency.

12. Taxes

Pieris shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Pieris under this Agreement. Roche agrees to reasonably assist Pieris in claiming exemption from such taxes and in minimizing the amount required to be so paid.

If provision is made in law or regulation of any country for withholding of taxes of any type, levies or other charges with respect to any royalty or other amounts payable under this Agreement to Pieris, then Roche shall promptly pay such tax, levy or charge for and on behalf of Pieris to the proper governmental authority, and shall promptly furnish Pieris with receipt of payment. Roche shall be entitled to deduct any such tax, levy or charge actually paid from royalty or other payment due to Pieris or be promptly reimbursed by Pieris if no further payments are due to Pieris. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

13. Auditing

13.1 Pieris' Right to Audit

Roche shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties payable under this Agreement. Such books of accounts shall be kept at their principal place of business. At the expense of Pieris, Pieris shall have the right to engage an independent public accountant reasonably acceptable to Roche to perform, on behalf of Pieris an audit of such books and records of Roche and its Affiliates, its licensees and Sublicensees, that are deemed necessary by Roche's independent public accountant to report on Net Sales of Product for the period or periods requested by Pieris, and the correctness of any financial report or payments made under this Agreement.

Upon timely request and at least [***] prior written notice from Pieris, such audit shall be conducted in the countries specifically requested by such independent public accountant, during regular business hours in such a manner as to not unnecessarily interfere with Roche's normal business activities, and shall be limited to results in the [***] prior to audit notification.

Such audit shall not be performed more frequently than [***] nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements, shall be treated as Roche's Confidential Information subject to the obligations of this Agreement and need neither be retained more than [***] after completion of an audit hereof, if an audit has been requested; nor more than [***] from the end of the Calendar Year to which each shall pertain; nor more than [***] after the date of termination of this Agreement.

13.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret the agreement. The auditors shall share all draft audit reports with Roche before the draft report is shared with Pieris and before the final document is issued. The final audit report shall be shared with Roche at the same time it is shared with Pieris.

13.3 Over- or Underpayment

If the audit reveals an overpayment, Pieris shall reimburse Roche for the amount of the overpayment within [***]. If the audit reveals an underpayment, Roche shall make up such underpayment with the next royalty payment or, if no further royalty payments are owed by Roche, Roche shall reimburse Pieris for the amount of the underpayment within [***]. Roche shall pay for the audit costs if the underpayment of Roche exceeds [***] of the aggregate amount of royalty payments owed with regard to the royalty statements subject to the audit. Section 11.2 shall apply to this Section 13.3.

13.4 Duration of Audit Rights

The failure of Pieris to request verification of any royalty calculation within the period during which corresponding records must be maintained under this Article 13 will be deemed to be acceptance of the royalty payments and reports.

14. Intellectual Property

14.1 Ownership of Pieris IP and Roche IP

Pieris shall remain the owner of Pieris IP, and Roche of Roche IP.

14.2 Ownership of Inventions

Pieris and Roche shall own Pieris Inventions and Roche Inventions, respectively. Joint Inventions shall be jointly owned by the Parties.

Notwithstanding the foregoing, Pieris shall own Inventions and Know-How solely related to improvements to the Pieris Technology, and Roche shall own Inventions and Know-How solely related to improvements to the Roche Technology. Each Party shall, to the extent legally permitted, require all of its employees to assign all Inventions related to such improvements made by them.

Pieris shall own any Inventions and Know-How related to [***]. Roche shall, to the extent legally permitted, require all of its employees to assign all Inventions related to [***] made by them.

Notwithstanding anything to the contrary in this Section 14, Roche shall own any Inventions and Know-How related to [***]. Pieris shall require all of its employees to assign all Inventions related to [***] made by them.

Except as specifically set forth herein, this Agreement shall not be construed as (i) giving any of the Parties any license, right, title, interest in or ownership to the Confidential Information; (ii) granting any license or right under any intellectual property rights; or (iii) representing any commitment by either Party to enter into any additional agreement, by implication or otherwise.

14.3 German Statute on Employee's Inventions

In accordance with the German Statute on Employees' Inventions, each Party agrees to claim the unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of, any research program by employees of any German Affiliates or any other persons acting on behalf of such German Affiliates. For the avoidance of doubt, each Party is responsible for fulfilling the obligations towards their employees under the German Statute of Employee's Inventions.

14.4 Prosecution of Patent Rights by Pieris

Pieris shall have the right to Handle its Patent Rights on Inventions assigned to Pieris pursuant to Section 14.2 at its own expense and with Roche's prior written consent (such consent not to be unreasonably withheld with regard to improvements to Pieris Technology) to the time point of filing any Patent Rights on such Inventions. When Handling its Patent Rights on Inventions made under this Agreement, Pieris shall, at its own expense, (i) consult with Roche as to the Handling of such Patent Rights, and (ii) furnish to Roche copies of all documents relevant to any such Handling. Pieris shall furnish such documents and consult with Roche in sufficient time before any action by Pieris is due to allow Roche to provide comments thereon, which comments Pieris must consider. At Pieris' expense and reasonable request, Roche shall cooperate, in all reasonable ways with the Handling of all of Pieris' Patent Rights relating to Inventions.

14.5 Prosecution of Patent Rights by Roche

Roche shall, at its own expense and discretion, Handle (including abandon) all its Patent Rights, including all Patent Rights claiming any [***], provided, however, that prior to abandoning of any Valid Claims of any Patent Rights related to [***], Roche shall provide reasonable advanced written notice to Pieris before abandoning such Patent Rights, in which case Pieris shall have the right to assume, at Pieris' cost, ownership of such Patent Rights as well as the right to continue maintenance thereof.

14.6 CREATE Act

It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in 35 USC §103(c)(3).

14.7 Defense

If the manufacture, use, importation, offer for sale or sale of any Product pursuant to this Agreement results in any claim, suit or proceeding alleging patent infringement or trade secret misappropriation against Pieris or a member of the Roche Group, then such Party shall promptly notify the other Party hereto. The Parties shall cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding.

If a Third Party asserts that Patent Rights owned by or licensed to it are infringed by the development, manufacture, use, importation, offer for sale or sale of Products by a member of the Roche Group, or that its trade secrets were misappropriated in connection with such activity, then Roche shall have the exclusive right and responsibility to resolve any such claim, whether by obtaining a license from such Third Party, by defending against such Third Party's claims or otherwise, and shall be solely responsible for the defense of any such action, any and all costs incurred in connection with such action (including, without limitation, attorneys' and expert fees) and all liabilities incurred in connection therewith. Notwithstanding the above, Roche shall not enter into any settlement of any such claim without the prior written consent of Pieris if such settlement would require Pieris to be subject to an injunction or to make any monetary payment to Roche or any Third Party, or admit any wrongful conduct by Pieris or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Patent Rights Controlled by Pieris, or have any impact on activities outside the Field.

If an action for infringement is commenced against Pieris, its licensees or its sublicensees related to Pieris's conduct of the research program within the scope of the Research Plan or the discovery of a Product, then Pieris shall have the right (but not the obligation) to defend such action at its own expense, and Roche shall assist and cooperate with Pieris, at Pieris' expense, to the extent necessary in the defense of such suit. Pieris shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long as such settlement or adverse judgment does not adversely affect the rights of Roche and its Affiliates (including any patent rights Controlled by any of them). Pieris shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party.

14.8 Enforcement

14.8.1 Enforcement of Patent Rights relating to [***]

Roche shall have the full and unrestricted right, but not the obligation, to bring and control an appropriate suit or other action against any person or entity engaged in any infringement action or proceeding to the extent directly relating to Patent Rights relating to [***], in its own name and entirely under its own direction and control. If Roche requests so, Pieris shall reasonably cooperate with Roche in the planning and execution of any such action to enforce such Patent Rights (including the obligation to be named or joined as a party in a lawsuit, as applicable). All monies recovered upon the final judgment or settlement of any such suit or action to enforce such Patent Rights subtracting any costs that Roche bore in connection with such suit or action shall be calculated as Net Sales. In the event that Roche does not wish to enforce such Patent Rights against such a potential infringer, then Roche shall deliver prompt written notice thereof to Pieris.

14.8.2 Enforcement of Patent Rights related to Pieris IP

Pieris shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in any infringement action or proceeding to the extent directly relating to Pieris IP and to Patents relating to [***] (but excluding Patents relating to [***]). If Pieris fails to commence a suit to enforce the applicable Pieris IP and to Patents relating to [***] or to settle or otherwise secure the abatement of such action or proceeding within a reasonable period, then Roche shall have the right, but not the obligation, to commence a suit or take action to enforce such Patent Rights against such infringement action or proceeding in the Field in the Territory at its own cost and expense, and only to the extent such action or proceeding is related to the Product(s).

14.9 Common Interest Disclosures

With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Research Plan and/or Compounds and/or Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the Research Plan and/or Compounds and/or Products. Accordingly, the Parties agree that all such information and materials obtained by Pieris and Roche from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

14.10 Biosimilar or interchangeable biological products

If Roche requests so, within four (4) years after the approval of a Product that has been licensed in the US as a biological product under 42 USC §262(a), and as may be needed from time to time thereafter, the Parties shall consult as to potential strategies with respect to unexpired US Patent Rights that Cover the Product. Specifically, in anticipation of a receipt by the Product's reference product sponsor ("**Reference Product Sponsor**") of a biosimilar or interchangeable product application pursuant to the Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148), the Parties will discuss the Reference Product Sponsor's likely course of action with regard to each such US Patent Right in the procedural steps set forth under 42 USC §262(l), including a general plan for timely communication between the Parties in light of the statutory response deadlines.

14.11 Patent Term Extensions

The Parties shall use Commercially Reasonable Efforts to obtain all available patent term extensions, adjustments or restorations, or supplementary protection certificates ("**SPCs**", and together with patent term extensions, adjustments and restorations, "**Patent Term Extensions**"). Pieris shall execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions, including designating Roche as its agent for such purpose as provided in 35 U.S.C. Section 156. All filings for such Patent Term Extensions shall be made by Roche; provided, that in the event that Roche elects not to file for a Patent Term Extension, Roche shall (a) promptly inform Pieris of its

intention not to file and (b) grant Pieris the right to file for such Patent Term Extension. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to such Patent Rights.

15. Representations and Warranties

15.1 Third Party Patent Rights

As of the Effective Date, Pieris has no knowledge of the existence of any patent or patent application owned by or licensed to any Third Party that could prevent Roche from making, having made, using, offering for sale, selling or importing [***] in the Territory.

15.2 Ownership of Patent Rights

Pieris is the exclusive owner of all right, title and interest in, or is the exclusive licensee, with the right to sublicense in the Field and in the Territory of, the Patent Rights related to Pieris IP.

15.3 Inventors

Pieris warrants that, for Patent Rights owned by Pieris and its Affiliates, the inventors of the Inventions disclosed and/or claimed in Pieris IP have transferred to Pieris full ownership of the patent rights and know-how licensed under this Agreement.

15.4 Grants

To the best of Pieris' knowledge and belief, Pieris has the lawful right to grant Roche and its Affiliates the rights and licenses described in this Agreement.

15.5 Authorization

The execution, delivery and performance of this Agreement by either Party and all instruments and documents to be delivered by a Party hereunder: (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of formation or limited liability company agreement of such Party; (iv) to the knowledge of such Party, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a party or by which such Party or any of its property is bound, which violation would have an adverse effect on the financial condition of such Party or on the ability of such Party to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously (other than approvals required under the HSR Act, Regulatory Approvals required for the sale of Products and filings with Regulatory Authorities required in connection with Products).

15.6 Validity of Patent Rights

As of the Effective Date, Pieris is not in possession of information that could render invalid and/or unenforceable any claims that are in any of the Patent Rights related to Pieris IP. Pieris has no knowledge of any inventorship disputes concerning any Patent Rights related to Pieris IP.

15.7 Ownership and Validity of Know-How

The Know-How of each Party is legitimately in the possession of such Party and has not been misappropriated from any Third Party. The Parties have taken reasonable measures to protect the confidentiality of its Know-How.

15.8 No Claims

There are no claims or investigations, pending or threatened against Pieris or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement and that would materially adversely affect Pieris' ability to perform its obligations hereunder.

15.9 No Conflict

Neither Party nor any of their respective Affiliates is or will be under any obligation to any person, contractual or otherwise, that is conflicting with the terms of this Agreement or that would impede the fulfillment of their respective obligations hereunder.

15.10 No Other Representations

EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS, VALIDITY AND ENFORCEABILITY OF ANY PATENT RIGHT LICENSED HEREUNDER, AND NON-INFRINGEMENT OF ANY PRODUCT.

16. Indemnification

16.1 Indemnification by Roche

Roche shall indemnify, hold harmless and defend Pieris and its directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Pieris becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of activities conducted by or on behalf of Roche under this Agreement, except to the extent such losses, expenses, costs and amounts are due to the gross negligence or willful misconduct or failure to act of Pieris.

16.2 Indemnification by Pieris

Pieris shall indemnify, hold harmless and defend Roche and its directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Roche becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of activities conducted by or on behalf of Pieris under this Agreement, except to the extent such losses, expenses, costs and amounts are due to the gross negligence or willful misconduct or failure to act of Roche.

16.3 Procedure

In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and

solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

17. Liability

17.1 Limitation of Liability

Subject to Section 4.2, neither Party shall be liable to the other Party as a result of failure or delay to develop and/or commercialize the Product(s), as applicable, including but not limited to, a) a delay in timelines, or b) delay or failure to recruit patients, or c) a change in its respective study protocols, or d) failure of the other Party to obtain regulatory approval for the Product(s), as applicable.

17.2 Disclaimer

THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY SET FORTH HEREIN. PIERIS AND ROCHE DISCLAIM ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO EACH OF THEIR RESEARCH, DEVELOPMENT AND COMMERCIALIZATION EFFORTS HEREUNDER, INCLUDING, WITHOUT LIMITATION, WHETHER THE PRODUCTS CAN BE SUCCESSFULLY DEVELOPED OR MARKETED, THE ACCURACY, PERFORMANCE, UTILITY, RELIABILITY, TECHNOLOGICAL OR COMMERCIAL VALUE, COMPREHENSIVENESS, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WHATSOEVER OF THE PRODUCTS. IN NO EVENT SHALL EITHER PIERIS OR ROCHE BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY.

18. Obligation Not to Disclose Confidential Information

18.1 Non-Use and Non-Disclosure

During the Agreement Term and for [***] thereafter, a Receiving Party shall (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to disclose such Confidential Information to Third Parties, without the Disclosing Party's prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations under this Agreement.

18.2 Permitted Disclosure

Notwithstanding the obligation of non-use and non-disclosure set forth in Section 18.1, the Parties recognize the need for certain exceptions to this obligation, specifically set forth below, with respect to press releases, patent rights, publications, and certain commercial considerations.

18.3 Press Releases

The Parties may issue a press release announcing the existence and selected key terms of this Agreement, as attached as Appendix 18.3.

Roche shall issue press releases in accordance with its internal policy that typically does not issue a second press release until proof of concept has been achieved for a Product. Roche shall provide Pieris with a copy of any draft press release related to the Agreement at least [***] prior to its intended publication for Pieris' review. Pieris may provide Roche with suggested modification to the draft press release. Roche shall consider Pieris' timely suggestions in issuing its press release.

Pieris shall only issue press releases related to the activities contemplated by this Agreement that have either (i) been approved by Roche (such approval not to be unreasonably withheld), or (ii) are required to be issued by Pieris as a matter of law and Pieris has a competent legal opinion to that effect. In all circumstances, Pieris shall provide Roche with a draft press release at least [***] prior to its intended publication for Roche's review. During such period, Roche shall (i) approve the draft press release and permit Pieris to issue the press release, (ii) contact Pieris to discuss modification to the draft press release, or (iii) contact Pieris and disapprove the press release. If Roche asks for modification, then Pieris shall either make such modification or work with Roche to arrive at a press release that Roche approves. If Pieris issues a press release without Roche's approval, then Pieris must obtain a competent legal opinion that the release was required to be issued by Pieris as a matter of law.

18.4 Publications

During the Agreement Term, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information relating to the Product in any publication or presentation:

a) Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines. Roche, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of Roche.

b) A Party ("**Publishing Party**") shall provide the other Party with a copy of any proposed publication or presentation at least [***] prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("**Publishing Notice**") the Publishing Party in writing, within [***] after receipt of the copy of the proposed publication or presentation, that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived and/or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (ii) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than [***] from the date of the Publishing Notice.

18.5 Commercial Considerations

(a) Nothing in this Agreement shall prevent Roche or its Affiliates from disclosing Confidential Information of Pieris to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product(s) in the Territory, (ii) Third Parties acting on behalf of Roche, to the extent reasonably necessary for the development, manufacture or sale of Product(s) in the Territory, or (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory, provided that for disclosures according to (ii) or (iii) of this Section, such Third Parties will be subject to the same confidentiality obligations as Roche has hereunder.

(b) Nothing in this Agreement shall prevent Pieris or its Affiliates from disclosing (1) Confidential Information of Roche to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product(s) in the Territory as provided for in Section 19.3.4, (ii) Third Parties acting on behalf of Pieris, to the extent reasonably necessary for (A) Pieris to perform its activities and obligations under the Research Plan, or (B) the development, manufacture or sale of Product(s) in the Territory as provided for in Section 19.3.4, or (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory as provided for in Section 19.3.4, or (2) to a Third Party the terms of this Agreement as part of confidential due diligence carried out by such Third Party in connection with a potential Change of Control of Pieris; provided that for disclosures according to (1) (ii) and (iii) or (2) of this Section, such Third Parties will be subject to the same confidentiality obligations as Pieris has hereunder.

(c) The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Law, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and, to the extent practicable, takes reasonable and lawful actions to minimize the degree of such disclosure.

19. Term and Termination

19.1 Commencement and Term

This Agreement shall commence upon the Effective Date and continue for the Agreement Term.

19.2 Termination

19.2.1 Termination for Breach

A Party ("**Non-Breaching Party**") shall have the right to terminate this Agreement in its entirety or on a country-by-country basis in the event the other Party ("**Breaching Party**") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach and the countries in which the Non-Breaching Party intends to have this Agreement terminate. The Breaching Party shall have a period of ninety (90) days after such written notice is provided ("**Peremptory Notice Period**") to cure such breach. If the Breaching Party has a dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party, and the expiration of the Peremptory Notice Period shall be tolled until such dispute is resolved pursuant to Section 21.2. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in such countries effective as of the expiration of the Peremptory Notice Period.

19.2.2 Insolvency

A Party shall have the right to terminate this Agreement, if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof.

19.2.3 Effects of Change of Control

If there is a Change of Control, then the Party experiencing such Change of Control ("**Acquired Party**") shall provide written notice to the other Party ("**Non-Acquired Party**") at least [***] to completion of such Change of Control, subject to any confidentiality obligations of the Acquired Party then in effect (but in any event shall notify the Non-Acquired Party within [***] after completion of such Change of Control).

The Change of Control Group in connection with such Change of Control shall agree in writing with the Non-Acquired Party that it will not utilize any of the Non-Acquired Party's Know-How, Patent Rights, Inventions, or Confidential Information (collectively, "**Sensitive Information**") for the research, development or commercialization of any product for the treatment of any indication or patient population for which a Product may be developed or commercialized.

Following consummation of the Change of Control, the Non-Acquired Party and the Change of Control Group shall adopt in writing reasonable procedures to prevent the disclosure of Sensitive Information beyond the Acquired Party's personnel who need to know the Sensitive Information solely for the purpose of fulfilling the Acquired Party's obligations under this Agreement. The Non-Acquired Party may restrict the Acquired Party's participation in the JRC and any other committee in effect at the time of the Change of Control, and decisions of the JRC and other such committees shall be made by Roche.

If there is a Change of Control of Pieris involving a company that develops or commercializes biopharmaceutical products (for clarity, generally for itself and not typically on a contract basis for other companies), then Roche may, in its sole discretion, immediately terminate the Agreement in its entirety. Upon any such termination by Roche, Pieris will immediately cease all activity and transfer to Roche all data developed by Pieris. Pieris shall provide an invoice to Roche specifying the, and reconcile [***] made by Roche. Within [***] of such reconciliation, Pieris will refund to Roche the difference between the [***] by Roche and Pieris actual FTE expenditures [***]. All licenses granted by Pieris to Roche shall remain in effect subject to the payment and diligence obligations under this Agreement. Pieris shall lose the right to query Roche for the [***] as foreseen in Section 2.4, and all licenses granted by Roche to Pieris shall terminate, except for the licenses under Section 2.4 with regards to licenses for [***] already granted and for which Pieris is [***] and provided that the Change of Control Group or its sublicensees develop such [***] without the use of any Sensitive Information. Further, the right to query Roche for the [***] and Roche's grant of licenses for such [***] as foreseen under Section 2.4 shall remain in effect provided that the Change of Control of Pieris involves a company as described above that, at the time of such Change of Control, (i) has a market capitalization of less than [***] US dollars (USD [***]) and (ii) has [***].

19.2.4 Voluntary Termination by Roche

Termination Without a Cause

After [***] from the Effective Date, Roche shall have the right to terminate this Agreement at any time as a whole, or on a Product-by-Product and country-by-country basis upon [***] prior written notice before First Commercial Sale of a Product or upon [***] prior written notice after the First Commercial Sale of a Product. For clarity, Roche shall have the right to provide written notice of termination before the end of the initial [***], but such termination shall only take effect when the initial [***] have ended.

Effective Date of Termination

The effective date of termination under this Section 19.2.4 shall be the date [***] (or [***] as the case may be) after Roche provides such written notice to Pieris.

19.3 Consequences of Termination

19.3.1 Termination by Pieris for Breach by Roche

Upon any termination by Pieris for breach by Roche, the rights and licenses granted by Pieris to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by-Product basis, as applicable, on the effective date of termination, and all licenses granted by Roche to Pieris under Section 2.4 shall remain in effect.

19.3.2 Termination by Roche for Breach by Pieris or Pieris' Insolvency

Upon any termination by Roche for breach by Pieris or Pieris' Insolvency, Roche and its Affiliates may upon notice retain all rights and licenses granted to Roche by Pieris under this Agreement; provided that after the effective date of termination the amounts of such payments and royalties that otherwise would have become due and payable shall continue to be due and payable to Pieris or its successor in interest (as applicable).

19.3.3 Voluntary Termination by Roche

Upon any voluntary termination by Roche, the rights and licenses granted by Pieris to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by Product basis, as applicable, on the effective date of termination, and all licenses granted by Roche to Pieris under Section 2.4 shall remain in effect.

19.3.4 Continuation Election Notice

In the case of termination by Pieris for breach by Roche (Section 19.3.1) or in case of voluntary termination by Roche (Section 19.3.3), if Pieris desires to continue development and/or commercialization of Product(s), Pieris shall give a Continuation Election Notice to Roche within [***] of receipt of Pieris' or Roche's notice of termination, as applicable, and pay [***] Swiss francs (CHF [***]) within [***] after receipt of respective invoice from Roche. If Roche receives such a timely Continuation Election Notice, and to the extent reasonably requested by Pieris:

a) At Roche's choice, Roche shall either grant to Pieris an exclusive (with respect to the terminated territory and Product only) and royalty free license to Patent Rights only to the extent covering Inventions relating to [***] that Roche received from Pieris under Section 14.2 and to the extent necessary to continue development and/or commercialization of the terminated Product in the terminated territory, or assign and transfer to Pieris such Patent Rights, free of charge. For clarity, if such Patent Rights also cover Inventions relating to [***] or other subject matters, the license to such Inventions shall be subject to Section 19.3.4 (b).

b) The Parties shall enter into good faith negotiations with regards to a royalty-bearing license, with the right to grant sublicenses (through multiple tiers), under intellectual property and rights owned by Roche not covered under Section 19.3.4 (a) and relating to Products [***] (for clarity, [***] are excluded from such license). Such license shall be under terms to be negotiated in good faith between the Parties, taking into account the value of such intellectual property and rights and the contribution made by Roche to the development of the Product(s) and their development stage. The good faith negotiations for a license described in this Section shall in particular address:

   i. The obligation of Roche to, to the extent Roche has the right to do so, transfer to Pieris all material regulatory correspondence, filings (including all Filings) and approvals (including all Regulatory Approvals), all final pre-clinical and clinical study reports and clinical study protocols, and all data, including clinical data, in Roche's possession or control related to Product(s) in the country useful or necessary for Pieris to continue to develop, manufacture and commercialize the Product(s). All data shall be transferred in the form and format in which it is maintained by Roche. Original paper copies shall only be transferred, if legally required. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to Pieris. In connection with research studies or clinical trials, Roche may have collected human samples and related clinical information for additional limited research and development programs ("**Samples**"). Legal and contractual restrictions may apply to such Samples, in particular as Samples may qualify as personal identifiable information. Roche shall transfer any such Samples to Pieris to the extent permitted by the informed consents as originally established with respect to such Samples and Applicable Laws.

   ii. Assignment of all clinical trial agreements and any other Third Party agreement relating to the development, manufacture or commercialization of a Product, to the extent such agreements have not been cancelled and are assignable without Roche paying any consideration or commencing litigation in order to effect an assignment of any such agreement (and the obligation of Roche to use Commercially Reasonable Efforts to obtain consent from the concerned Third Party to such a transfer).

   iii. The obligation of Pieris to [***] incurred by or on behalf of Roche for transfer activities from Roche to Pieris to the extent such costs and expenses exceed the fee of [***] Swiss francs (CHF [***]) paid by Pieris under this Section.

iv. The obligation of Pieris to pay royalties to Roche on Net Sales of such Product(s). Such royalties shall be dependent on the then-current development stage of the Product(s) according to the following table:

Development stage of Product(s)	Royalty rate
Prior to start of Phase II Study	[***]
After start of Phase II Study but before Start of Phase III Study	[***]
After Start of Phase III Study but before First Commercial Sale	[***]
After First Commercial Sale	[***]

The above royalty rates shall be reduced by [***] on a Product-by-Product and country-by-country basis in each country in which the manufacture, use, sale or import of the Product(s) is not covered by a Composition of Matter Claim of Roche.

Pieris' obligation to pay royalties to Roche shall, with respect to such Product(s) and for a given country, start on the date of First Commercial Sale of such Product(s) in such country and end on the later of the date that is (a) [***] after the date of the First Commercial Sale of such Product(s) in such country, or (b) the expiration of the last to expire Composition of Matter Claim of a patent owned or Controlled by Roche (or by Pieris pursuant to Sections 14.5 or 19.3.4) in such country Covering the use, import, offering for sale, or sale of such Product(s). Sections 10.6.3.2, 10.7 and 10.8 shall apply mutatis mutandis to the royalty rate owed by Pieris to Roche.

v. The obligation of Roche to manufacture and supply the Product(s) to Pieris during a transition period at [***], until such time as Pieris has procured or developed its own source of Product supply, provided that Pieris can demonstrate it has been diligently seeking an alternative manufacturer and provided further that in any case Roche's manufacture and supply obligation shall in no event exceed [***] from the effective date of the termination of this Agreement, except as provided below. Pieris shall use Commercially Reasonable Efforts to establish or take over the manufacturing as soon as possible after the effective date of termination. In case termination occurs before Phase II Studies have been Initiated, Pieris shall, at the request of Roche, use Commercially Reasonable Efforts to develop their [***] to be used in pivotal studies. In case termination occurs when Phase II Studies have already been Initiated or later, Roche shall reasonably cooperate in assisting Pieris in the transfer of manufacturing process for such Product to a Third Party manufacturer, provided such Third Party manufacturer is acceptable to Roche; and Roche shall transfer the [***] to such Third Party manufacturer. Except as provided herein, Roche shall be under no obligation to provide, transfer or allow Pieris to use proprietary [***], or disclose proprietary [***] related to the Product(s). In case termination occurs after Initiation of Phase III Studies, Roche shall, upon Pieris' request, [***] for the manufacture of Product(s) to the Third Party manufacturer acceptable to Roche.

vi. In case the necessary transfers under subsections (i), (ii) and (v) have not been achieved within the foreseen timelines due to difficulties not under control of the Parties, then Roche shall reasonably cooperate and assist Pieris for a reasonable additional period not to exceed [***] (such difficulties can consist in, for example, a regulatory approval being delayed).

c) For clarity, the licenses under this Section 19.3.4.a) and b) shall not include (i) any licenses that Roche has with a Third Party for which such grant would be prohibited or under which a member of the Roche Group would incur financial obligations to such Third Party, provided, however, that Roche shall (a) sublicense such Third Party licenses to Pieris if allowed in the respective license agreement, subject to Pieris committing to assume full responsibility for any and all financial obligations owed by Roche to such Third Party for the sublicense, and (b) reasonably support Pieris in getting in contact with such Third Party, for which a sublicense is not permitted, to get access to such Third Party rights, and (ii) the Excluded Patent Rights.

19.3.5 Direct License

Irrespective of anything to the contrary in this Agreement, any existing, permitted sublicense granted by Roche under Section 2.3 of this Agreement (and any further sublicenses thereunder) shall, upon the written request of Roche, remain in full force and effect, provided that (i) such Sublicensee is not then in breach of its sublicense agreement (and, in the case of termination by Pieris for breach by Roche, that such Sublicensee and any further sublicensees did not cause the breach that gave rise to the termination by Pieris); and (ii) and such Sublicensee agrees to be bound to Pieris under the terms and conditions of such sublicense agreement, provided that the payments due to Pieris by such Sublicensee under such sublicense agreement are no less than the payments that would have been due to Pieris by Roche under this Agreement.

19.3.6 Other Activities

19.3.6.1 Ongoing Activities

If Pieris does not provide timely Continuation Election Notice (Section 19.3.4), then Roche (a) shall have the right to cancel all ongoing activities and (b) shall complete all non-cancellable activities at its own expense.

If Pieris provides such timely Continuation Election Notice, then from the date of notice of termination until the effective date of termination, Roche shall, at Pieris' request and expense, continue activities performed by or on behalf of Roche, including preparatory activities, ongoing as of the date of notice of termination. However, subject to Section 19.3.4, Roche shall not be obliged to initiate any new activities not ongoing at the date of notice of termination.

After the effective date of termination and to the extent that Pieris has not made a request as described above, Roche shall not have any obligation to perform and/or complete any activities or to make any payments for performing or completing any activities under this Agreement, except as expressly stated herein.

19.3.6.2 Royalty and Payment Obligations

Termination of this Agreement by a Party, for any reason, shall not release Roche from any obligation to pay royalties or make any payments to Pieris that are due and payable prior to the effective date of termination.

19.4 Survival

Section 11.2 (Late Payment), Article 13 (Auditing), Article 14 (Intellectual Property), Article 16 (Indemnification), Article 18 (Obligation Not to Disclose Confidential Information), Article 19 (Term and Termination), Section 21.1 (Governing Law), Section 21.2 (Disputes), Section 21.12 (Notice) and all definitions used in such Articles and Sections shall survive any expiration or termination of this Agreement for any reason.

20. Bankruptcy

All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by Pieris to Roche are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, US Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. Unless Roche elects to terminate this Agreement, the Parties agree that Roche, as a licensee or sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, subject to the continued performance of its obligations under this Agreement.

21. Miscellaneous

21.1 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of Germany, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

21.2 Disputes

(a) Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or their designees, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For Pieris: CEO
For Roche: Head of Roche Partnering

(b) Should the Parties fail to agree within [***] after such dispute has been referred to the Parties' designated executive officers, then either Party shall be entitled to request resolution of the dispute through arbitration, which shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said Rules. The place of arbitration shall be Basel, Switzerland. The language to be used in the arbitration proceeding shall be English.

21.3 Assignment

Neither Party shall have the right to assign the present Agreement or any part thereof to any Third Party other than Affiliates without the prior written approval of the other Party which shall not unreasonably be withheld, provided however, if a Party is acquired or is to be acquired by a third party by merger, acquisition, or the sale of substantially all of the assets of the division of such Party to which the subject matter of this Agreement relates, then such Party may effect such an assignment or transfer to such acquiring Third Party without the consent of the other Party.

21.4 Debarment

Each Party represents and warrants that it has never been debarred or otherwise sanctioned by the FDA, or a corresponding regulatory authority. Neither Party has been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event either Party receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, such Party shall immediately notify the other Party in writing and such other Party shall have the right, but not the obligation, to terminate this Agreement, effective, at such Party's option, immediately or at a specified future date.

21.5 Independent Contractor

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Pieris' legal relationship to Roche under this Agreement shall be that of independent contractor.

21.6 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.7 Waiver

The failure by either Party to require strict performance and/or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance and/or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition.

21.8 Appendices

All Appendices to this Agreement shall form an integral part to this Agreement.

21.9 Entire Understanding

This Agreement contains the entire understanding between the Parties hereto with respect to the within subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral.

21.10 Amendments

No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

21.11 Invoices

All invoices that are required or permitted hereunder shall be in writing and sent by Pieris to Roche at the following address or other address as Roche may later provide:

F. Hoffmann-La Roche Ltd
[***]
Switzerland

21.12 Notice

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Pieris, to:	Pieris Pharmaceuticals GmbH Lise-Meitner-strasse 30 85354 Freising Germany Attn: CEO Facsimile No.: [***]
and:	Pieris Pharmaceuticals, Inc. 255 State Street, 9th floor Boston, MA 02109 U.S.A Attn: CEO Facsimile No.: [***]
if to Roche, to:	F. Hoffmann-La Roche Ltd [***] Switzerland Attn: Legal Department Facsimile No.: [***]
and:	Hoffmann-La Roche Inc. [***] U.S.A. Attn. Corporate Secretary Facsimile No.: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

Pieris Pharmaceuticals GmbH

/s/ Stephen S. Yoder
Name: Stephen S. Yoder
Title: President & CEO

Pieris Pharmaceuticals, Inc.

/s/ Stephen S. Yoder
Name: Stephen S. Yoder
Title: President & CEO

F. Hoffmann-La Roche Ltd

/s/ Vikas Kabra
Name: Vikas Kabra
Title: Head of Transaction Excellence

/s/ Dr. Christof Burri
Name: Dr. Christof Burri
Title: Legal Counsel

Hoffmann-La Roche Inc.

/s/ John P. Parise
Name: John P. Parise
Title: Authorized Signatory

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

CONFIDENTIAL TREATMENT REQUESTED

Appendix 1.60

Pieris IP

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Appendix 1.66

Research Plan

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Appendix 1.68

Excluded Patent Rights

[***]

CONFIDENTIAL TREATMENT REQUESTED

Appendix 1.74

[***]

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Appendix 18.3

Press Release

PRESS RELEASE

Pieris Pharmaceuticals Announces
First Cancer Immunotherapy Collaboration

Agreement with Roche Leverages Proprietary Anticalin® Technology Platform

Boston, MA, December 8, 2015 – Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a biotechnology company advancing novel bio therapeutics through its proprietary Anticalin® technology platform, today announced a research collaboration and license agreement with Roche in cancer immunotherapy (CIT). Under the terms of the agreement, Pieris will discover, characterize and optimize Anticalin®-based drug candidates against an undisclosed target. Roche and Pieris will evaluate different drug formats against this target and advance them through preclinical development, with Roche being responsible for IND-enabling activities, clinical development and worldwide marketing of any resulting products. Pieris will receive an upfront payment of CHF 6.5 million (~$6.4 million USD) and committed research funding, and may receive development and regulatory-based milestone payments, sales-based milestone payments as well as mid single-digit to low double-digit royalties on any future product sales. If all milestones and other conditions are met, the total payments to Pieris could surpass CHF 415 million (~$409.3 million USD), excluding royalties.

“Our partnership with Roche is a significant step forward for Pieris,” commented Stephen Yoder, President and CEO of Pieris. “The decision by the leader in the development and commercialization of cancer biologics to collaborate with Pieris underscores the unique potential of Anticalin-based proteins as a differentiated class of immuno-oncology drugs. As we initiate this collaboration, we will continue to vigorously advance our fully proprietary programs, including our lead CD137-HER2 bispecific.”

With its immuno-oncology PRS-300 Series, which remains proprietary to the Company, Pieris is developing bispecific Anticalin-based protein therapeutics against a variety of tumor and immunomodulatory targets. These compounds, including its lead program PRS-343 (CD137/HER2 bispecific), aim to activate the immune system in the tumor microenvironment, with the goal of increasing efficacy as well as improving safety compared to existing approaches. This collaboration represents Pieris’ first partnered immuno-oncology program and leverages Pieris’ capability to address a target in multiple ways through Anticalin-based drug candidates in different formats.

Portions of the exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

About Pieris Pharmaceuticals:

Pieris Pharmaceuticals is a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumour micro-environment, an inhaled Anticalin to treat uncontrolled asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin®, Anticalins® are registered trademarks of Pieris. For more information visit www.pieris.com.

About Anticalins:

Anticalins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies.

Anticalin®, Anticalins® are registered trademarks of Pieris.

Forward Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business, research and product development plans; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business, research and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and the Company's Quarterly Reports on Form 10-Q.

Portions of the exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

CONFIDENTIAL TREATMENT REQUESTED

Company Contact:
Pieris Pharmaceuticals, Inc.
Darlene Deptula-Hicks
SVP and Chief Financial Officer
+1-603-553-5803
deptula@pieris.com

Investor Relations Contact:
The Trout Group
Thomas Hoffmann
+1-646-378-2931
thoffmann@troutgroup.com

or

The Del Mar Consulting Group, Inc.
Robert Prag, President
+1-858-794-5000
bprag@delmarconsulting.com

Media Inquiries:
Gretchen Schweitzer
+49 172 861 8540
gschweitzer@macbiocom.com

##END##

***Portions of the exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

Exhibit 21.1

Subsidiaries

Entity	Jurisdiction of Organization
Pieris Pharmaceuticals GmbH	Germany
Pieris Australia PTY Ltd.	Australia

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Stephen S. Yoder, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Stephen S. Yoder

Stephen S. Yoder
Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Darlene Deptula-Hicks, certify that:

1. I have reviewed this annual report on Form 10-K of Pieris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Darlene Deptula-Hicks
Darlene Deptula-Hicks
Title: Chief Financial Officer
(principal accounting and financial officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc. a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2016

/s/ Stephen S. Yoder

Stephen S. Yoder
Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 32.2

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Pieris Pharmaceuticals, Inc. a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2016

/s/ Darlene Deptula-Hicks

Darlene Deptula-Hicks
Title: Chief Financial Officer
(principal accounting and financial officer)